

Exhibit 161

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION IX

**Response to the November 2005 National Stone, Sand & Gravel Association
Report Prepared by the R.J. Lee Group, Inc
“Evaluation of EPA’s Analytical Data from the El Dorado Hills Asbestos
Evaluation Project”**

April 20, 2006



**United States Environmental Protection Agency Region 9
Response to the November 2005 National Stone, Sand & Gravel Association report
prepared by the R.J. Lee Group, Inc:
“Evaluation of EPA’s Analytical Data from the El Dorado Hills
Asbestos Evaluation Project”**

This document constitutes the United States Environmental Protection Agency Region 9 (EPA Region 9) response to the major findings and conclusions of the National Stone, Sand & Gravel Association report “Evaluation of EPA’s Analytical Data from the El Dorado Hills Asbestos Evaluation Project” prepared by the R. J. Lee Group (R. J. Lee Report). A more detailed analysis will be completed after additional information is received from the R. J. Lee Group and the National Stone, Sand & Gravel Association,¹ and the United States Geological Survey (USGS).

The R. J. Lee Report draws conclusions that are contradicted by the El Dorado Hills data and by generally accepted scientific principles for measuring asbestos exposure.

Overview

The R. J. Lee Group review of the EPA data was contracted by the National Stone, Sand & Gravel Association. The El Dorado County Office of Education funded the three reviewers who wrote letters in support of the R. J. Lee Report and whose reviews are included in this response.

The EPA Region 9 El Dorado Hills Naturally Occurring Asbestos Exposure Assessment was designed to measure the exposures to asbestos fibers, if any, that resulted from sports and play activities that disturbed dust and soil. EPA Region 9 adhered to accepted EPA standards for sampling and analysis, including rigorous quality assurance/quality control, and to the standard methodologies of EPA exposure and risk assessment.

The R. J. Lee Report Criticizes EPA Region 9 for Using Established Scientific and Public Health Protocols - In assessing naturally occurring asbestos exposures in El Dorado Hills, EPA evaluated asbestos exposures using the PCME (phase contrast microscopy equivalent) asbestos fiber size classification. The PCME classification was used because human epidemiological studies, which form the basis of knowledge of asbestos health effects, measured asbestos fiber concentrations using phase contrast microscopy (PCM) analytical methods. PCME is the standard term for fibers counted by more modern analytical methods that are of equivalent size to those fibers that would be seen by PCM analysis, and includes fibers with a length to width aspect ratio of 3 to 1 or greater. EPA considered PCME fibers in our analysis of the El Dorado data to be consistent with the existing health databases and risk assessment

¹On March 9, 2006, EPA Region 9 sent a letter to the R.J. Lee Group and the National Stone, Sand, & Gravel Association asking for additional information to support the findings and conclusions of the R.J. Lee Report.

procedures used by EPA, California EPA (Cal/EPA), the World Health Organization, and other federal agencies and international organizations. This approach was rejected by the R.J. Lee Group, which instead advocates use of asbestos fiber definitions which are not health based or supported by the majority of experts in the health community, and which would not allow comparison to the existing epidemiologic data on asbestos related cancers.

The R. J. Lee Report Claims that EPA Region 9 Misapplied Fiber Counting

Protocols - The R. J. Lee Report claims that EPA Region 9 inflated the fiber counts in the El Dorado Hills air data by misapplying the International Standards Organization (ISO) method 10312 (the analytical method used by EPA to analyze the El Dorado air samples) and including PCME structures with a 3 to 1 length to width aspect ratio in our analysis. The R. J. Lee Report maintains that EPA should only have counted structures which met the general 5 to 1 aspect ratio fiber size definition described in the body of the ISO 10312 method. However, Annex C and Annex E of the ISO 10312 method specifically authorize the counting of PCME structures with a 3 to 1 aspect ratio. Another example of misleading information is the R.J. Lee Report's statistical evaluation and resulting conclusions regarding the concentrations of asbestos structures detected in the EPA air samples. All of the established EPA, National Institute of Occupational Safety and Health (NIOSH), and ISO analytical methods require the counting of asbestos bundles, recognizing the significance of bundles to proper characterization of asbestos fiber levels. The R.J. Lee Report did not include asbestos bundles in its analysis of the data, thereby undercounting the number of structures.

The R. J. Lee Report Claims that EPA Region 9 Misidentified Amphibole Minerals -

The R. J. Lee Report concludes that EPA misidentified actinolite asbestos fibers in the El Dorado soil samples by using inappropriate extinction angle criteria. The R. J. Lee Group conclusion is contradicted by the National Institute of Standards and Technology (NIST) and the major analytical methods used for analysis of asbestos in soil and bulk samples. The R. J. Lee Report also cites an unpublished 1980 draft report to support its contention that structures found in the EPA air samples are not asbestos, and ignores a subsequent 1981 published report by the same author that actually supports the EPA approach.

The R. J. Lee Report Applies a Geologic Definition rather than a Public Health

Definition to Characterize Microscopic Structures - The R. J. Lee Report relies heavily on the geologic distinction between asbestos fibers and cleavage fragments of the same dimensions, with the implication that exposure to cleavage fragments is benign and of little or no health significance. For the purposes of public health assessment and protection, EPA makes no distinction between fibers and cleavage fragments of comparable chemical composition, size, and shape. The EPA Region 9 approach, which is supported by most public health agencies and scientists, as well as the American Thoracic Society, is based on the following: (1) The epidemiologic and health studies underlying EPA and Cal/EPA cancer risk assessment methods were based on exposures to both cleavage fragments and fibers, and were unable to distinguish between the two, (2) The most recent panel of experts to review asbestos risk assessment methods, the 2003 Peer Consultation Panel convened by EPA, concluded that "it is prudent at

this time to conclude equivalent potency [of cleavage fragments and fibers] for cancer,"² (3) No well-designed animal or epidemiological studies have adequately tested the hypothesis that cleavage fragments with the same dimensions as a fiber are benign or that the human body makes any distinction, (4) Studies that purport to show that cleavage fragments are benign are questioned by many asbestos health experts, (5) There are no routine asbestos air analytical methods, including those used by EPA, NIOSH, the Mine Safety and Health Administration (MSHA), the American Society for Testing and Materials (ASTM), and ISO which differentiate between cleavage fragments and crystalline fibers on an individual fiber basis.

The R. J. Lee Report's "Virtual" Review of EPA Region 9's Air Samples is Inconsistent with Established Laboratory Practices - The R.J. Lee Group did not have access to EPA's actual air samples, nor did it collect any air samples of its own. Rather it reviewed limited pictures and spectra data of a small number of EPA's air samples and drew conclusions based on those representations. Such a virtual review is not consistent with the National Voluntary Laboratory Assurance Program (NVLAP) quality assurance procedures nor the verification methods of the National Institutes of Standards and Technology.

Federal Courts Have Supported EPA - Many of the assertions of the R. J. Lee Report are consistent with positions that the R.J. Lee Group took as an expert witness for W.R. Grace in the Libby, Montana litigation. In this litigation, the written opinions of the District and Appeals courts, while not specifically addressing the opinions of the R.J. Lee Group, rule in favor of EPA and expressly hold that EPA's experts and science are credible.³

Background

In October 2004, the EPA Region 9 Superfund site assessment program conducted an assessment of exposures to naturally occurring asbestos (NOA) in El Dorado Hills, California. Specifically, EPA Region 9 simulated the sports activities of children and adults at three schools and a community park and, using personal air monitors, measured asbestos levels in the breathing zones of participants. EPA Region 9 also collected samples of ambient air in the area of the sampling at the same time the simulations were conducted to serve as reference samples. The personal activity-based samples were then compared to the reference samples. The Asbestos Hazard Emergency Response Act (AHERA)⁴ regulation Z-test for statistical

²USEPA (U.S. Environmental Protection Agency) (2003). Report on the Peer Consultation Workshop to Discuss a Proposed Protocol to Assess Asbestos-Related Risk, Final Report. Office of Solid Waste and Emergency Response, Washington D.C. Page viii.

³ See U.S. v. W.R. Grace, 280 F Supp 2d 1149 (2003); U.S. v. W.R. Grace, 429 F. 3d 1224, 1245 (9th Cir. 2005) (Although debate regarding testing methodology and data analysis is "exceedingly complex", EPA did not ignore accepted scientific principles)

⁴The Asbestos Hazard Emergency Response Act (AHERA) was passed by Congress in 1986 to provide for the inspection and mitigation of asbestos in school buildings. Regulations implementing the Act were promulgated by EPA in 1987.

significance was applied to determine whether there were any statistically significant differences between the personal exposure samples and the ambient reference samples. EPA Region 9 collected over 400 air samples and generated over 7000 data points. All of EPA Region 9's analyses were conducted by accredited laboratories using recognized methods and procedures with strict quality assurance control, including blind performance samples to check analytical accuracy.

Amphibole asbestos, which many health scientists consider to be even more toxic than chrysotile asbestos, was found in almost all the reference and activity-based samples. Of the 29 different sets of activity-based scenario measurements, application of the Z-test determined that personal exposures from 24 scenarios were significantly elevated over the reference samples. Most importantly, the data showed that children and adults participating in sports activities in areas where asbestos occurs naturally in the surface soils, as it does in El Dorado Hills, can be exposed to asbestos fibers of health concern at up to 62 times the corresponding reference levels.

EPA Region 9 released the data from the assessment in May 2005 and held a public meeting in El Dorado Hills that was attended by more than 1000 members of the public. From the outset of the assessment, EPA Region 9 made clear to the community that EPA's only intent was to gather data on potential exposures. The community and the State and local regulatory agencies could then use the information to make decisions about the significance of those exposures and determine appropriate control measures. Both EPA Region 9 and the Agency for Toxic Substances and Disease Registry (ATSDR) have informed the community that exposure levels are a main determinant of the risk of developing asbestos-related cancers and non-cancer diseases, and that reducing the exposures reduces the risk. Consistent with its intent, EPA Region 9 has actively engaged the State and local regulatory agencies to improve naturally occurring asbestos mapping, monitoring, dust control, and regulation. El Dorado County has recently adopted more stringent dust control ordinances.

Detailed Comments on the R. J. Lee Report

R.J. Lee Finding #1: “Based on Mineralogy, Sixty-Three Percent (63%) of the Amphibole Particles Identified as Asbestos Fibers can not be Asbestos.”

The R. J. Lee Report argues that there is too much aluminum in 63% of EPA Region 9's identified fibers for the fibers to be asbestiform.⁵ In addition, the remaining 37% (sometimes the Report uses 35%) are not asbestos fibers based on their particle dimensions.

EPA Response

Aluminum - Analysis of the EPA Region 9 El Dorado air samples was performed using the International Standards Organization (ISO) method 10312, a state-of-the-art

⁵Asbestiform: Having the form or structure of asbestos.

Transmission Electron Microscope (TEM)⁶ method with energy dispersive spectroscopy (EDS)⁷ that has strict counting rules and characterizes the dimensions and chemistry of every fiber identified by the microscopist. Identification of fiber type was performed according to the general guidelines of the International Mineralogical Association (IMA) (Leake, 1997)⁸, the international standard for amphibole nomenclature. This same approach for asbestos classification is recommended in the “Research Method for Sampling and Analysis of Fibrous Amphibole in Vermiculite Attic Insulation”, EPA 600/R-04/004, January 2004, and was one of the tools used by Meeker et al (2003)⁹ to determine the composition and morphology of amphiboles from Libby, Montana.

The R. J. Lee Report claims that 63% of the amphibole fibers identified by the EPA laboratory¹⁰ as actinolite asbestos have concentrations of total aluminum that are too high to form asbestos fibers. According to page 2 of the R. J. Lee Report, “Particles with more than 0.3 aluminum atoms pfu [per formula unit] or about 1.5 percent Al₂O₃, cannot form in the asbestos habit due to crystal lattice constraints.” To support its argument, the R. J. Lee Report cites three references. However, on close examination, two of the three references do not agree with the upper threshold limit that the R.J. Lee Group puts on total aluminum content (Leake et al, 1997) (Deer, Howie and Zussman, 1997)¹¹. The third reference (Verkouteren & Wylie, 2000)¹² draws its conclusions on examination of a

⁶Transmission Electron Microscopy (TEM) produces images of a sample by illuminating the sample with an electron beam in a vacuum, and detecting the electrons that are transmitted through the sample.

⁷Energy Dispersive Spectroscopy (EDS) uses measurement of the energy and intensity of X-rays generated when a selected area of a sample is irradiated with an electron beam to identify the mineralogical composition of a structure.

⁸B.E. Leake et al (1997). Nomenclature of Amphibole: Report of the Subcommittee on Amphiboles of the International Mineralogical Association, Commission on New Minerals and Mineral Names. American Mineralogist, Volume 82, pages 1019-1037.

⁹G.P. Meeker et al (2003). The Composition and Morphology of Amphiboles from the Rainy Creek Complex, Near Libby, Montana. American Mineralogist, Volume 88, pages 1955-1969.

¹⁰In this document, the terms “EPA laboratory” and “EPA Region 9 laboratory” refer to the private laboratories that conducted the analysis of the EPA soil and air samples under contract to EPA Region 9.

¹¹W.A. Deer, R.A. Howie, and J. Zussman (1997). Rock-Forming Minerals: Double Chain Silicates, Vol 2, second edition, p 137 - 145.

¹²J.R. Verkouteren and A.G. Wylie (2000). The Tremolite-Actinolite-Ferro-Actinolite Series: Systematic Relationships Among Cell Parameters, Composition, Optical Properties, and

small set of fibrous actinolite asbestos samples which the authors partition into asbestos and fibrous “non-asbestos” byssolite using criteria which the IMA specifically recommends against, and which is inconsistent with all standard asbestos analytical methods. Perhaps most important is the fact that all three references agree that it is the IMA criteria which primarily govern the general classification of amphibole type, not the total aluminum content. These references therefore actually support the classification approach taken by the EPA laboratory.

The R.J. Lee Group did not have access to the EPA air samples to conduct their own analyses. Instead, the R.J. Lee Group looked at a limited number of photographs of the recorded EDS spectra. Interferences by other elements in the sample can affect the aluminum total in the spectra. This is especially important because the EPA samples were of air releases from soil, not processed asbestos material. Soils contain non-asbestos mineral and biological particles that can influence element totals in an EDS spectrum, most notably clay particles, which are high in aluminum. The laboratory used by EPA Region 9 identified aluminum-rich actinolite asbestos, by applying the IMA classification guidelines to its direct analysis of the actual sample.¹³

Particle Dimension - As previously stated, the R. J. Lee Report claims that 37% of the fibers counted by EPA in the El Dorado Hills air samples are not asbestos fibers based on their particle dimensions. The report claims that EPA Region 9 inflated the fiber counts by including asbestos structures which do not meet the definition of a fiber as described in ISO 10312. The general ISO 10312 method requires the counting of every asbestos structure with a length to width aspect ratio of 5:1 or greater. As directed by Region 9, the EPA laboratory counted structures with a 3:1 or greater aspect ratio. The R. J. Lee Report states that EPA erred in counting structures with aspect ratios less than 5:1.

Annex C and Annex E of the ISO method clearly authorize the counting of PCME structures with a 3:1 aspect ratio if the data are to be used for exposure or risk assessment purposes, the stated goal of the El Dorado Hills assessment. In fact, the ISO method contains numerous references to PCME fibers. PCME fibers are defined as fibers greater than 5 microns in length, and 0.25 to 3 microns in width with a 3:1 aspect ratio.¹⁴ PCME fibers form the basis for EPA’s IRIS toxicity database and the asbestos risk models of California EPA and other federal and international organizations.¹⁵

Habit, and Evidence of Discontinuities. American Mineralogist, 85, p. 1239 - 1254.

¹³Personal communication with John Harris, Lab/Cor, January 2006.

¹⁴World Health Organization (1986). Environmental Health Criteria 53, International Programme on Chemical Safety, Asbestos and Other Natural Mineral Fibres, section 2.3.2.2.

¹⁵The IRIS asbestos cancer inhalation unit risk, a measure of asbestos cancer potency, is based on the EPA 1986 Airborne Asbestos Health Assessment Update (EPA/600/8-84/003F; 1986). Cal/EPA used a similar approach and data sets to derive its cancer unit risk. Both the IRIS and the Cal/EPA cancer potency values rely on human epidemiological studies that were conducted using phase contrast microscopy (PCM) analytical methods (some were midget

The R.J. Lee Group also manipulates its statistical analysis of the El Dorado Hills air data by ignoring counts of asbestos fiber bundles in its evaluations. Bundles are two or more attached parallel asbestos fibers which can have a significant health impact when they are inhaled and separate into individual fibers. Bundles were counted in the historical epidemiological studies which form the basis of our knowledge of asbestos-related health effects and EPA's IRIS database. **All of the established EPA, NIOSH, and ISO analytical methods require the counting of asbestos bundles, recognizing the significance of bundles to proper characterization of asbestos fiber levels.**

The R. J. Lee Report further states that EPA's data inflated the asbestos fiber count by ignoring the Agency's own "definition" of asbestos. To support this claim, the R.J. Lee Report cites the glossary of "Method for Determination of Asbestos in Bulk Building Materials", EPA 600/R-93/116, 1993, which states, in part, "With the light microscope, the asbestos habit is generally recognized by the following characteristics: Mean aspect ratios ranging from 20:1 to 100:1 or higher for fibers longer than 5 microns." The building material analytical method is designed to detect commercially processed asbestos in items like floor tiles, roofing felts, paper insulation, paints, and mastics, not naturally occurring asbestos on air filters or in soil samples. To present the 20:1 aspect ratio for commercial grade asbestos as a universal EPA policy, and to advocate its use as an appropriate standard for analyzing air samples of naturally occurring asbestos is inappropriate and contradictory to use of the PCME dimensional criteria as a tool for assessing exposure risk.

The R. J. Lee Report also states that the diffraction pattern analyses produced by the EPA laboratory for the El Dorado Hills air samples demonstrates that the particles identified by the laboratory are not asbestos.¹⁶ The report cites a 1980 unpublished draft study by S.J. Ring to support its conclusion. The R. J. Lee Report does not mention a 1981 published article by the same author which revises the findings such that they no longer support the conclusion of the R. J. Lee Report and, in fact, support the data produced by

impinger data converted to PCM counts) that could not distinguish fibers that were 5 microns in length or less. PCM cannot distinguish between fibers and cleavage fragments. PCM is not as powerful as current Transmission Electron Microscope (TEM) methods (400X vs 20,000X) as TEM can see the thinner/shorter fibers. However, since EPA's (and Cal/EPA's) toxicity database relies on human health studies that used PCM, current EPA risk procedures use the more powerful TEM method but report the PCM equivalent (PCME) fibers and only use the PCME counted fibers in a risk assessment. This is because the IRIS asbestos file specifies that only PCME fiber counts be used with inhalation unit risk for risk calculation. See also the reference cited in footnote 11.

¹⁶Diffraction pattern analyses irradiates a sample with x-rays and then takes an x-ray photograph.

EPA.¹⁷

R.J. Lee Finding #2: “The Laboratory Procedures did not Comply With the NVLAP Quality Assurance Standard.”

The R. J. Lee Report says that the false positive rate in our air samples was 35% when the acceptable limit in the National Voluntary Laboratory Accreditation Program (NVLAP) is 10%.

EPA Response

The laboratories used by EPA Region 9 for analysis of the El Dorado Hills air and soil samples are accredited through the National Voluntary Laboratory Accreditation Program (NVLAP). NVLAP is administered by the National Institute of Standards and Technology, a non-regulatory agency within the U.S. Commerce Department. A large part of the accreditation process involves on-site audits performed by NVLAP-certified inspectors who review laboratory operational and quality assurance compliance parameters, including documentation proving compliance with NVLAP requirements for verification analyses. A laboratory must demonstrate that all analysts reporting data meet the false negative and false positive requirements set forth by NVLAP before an accreditation certificate is issued. To make a determination that a laboratory did not comply with NVLAP verification standards would require a very detailed examination of all laboratory generated raw data, project specific information, such as a site-specific EPA issued Quality Assurance Project Plan, laboratory instrument log books, and other data and information not supplied in an analytical report. Interviews with the laboratory manager, quality assurance manager, and involved analysts are also mandatory to make judgement on a laboratory’s possible non-compliance. The R.J. Lee Report’s conclusion that the EPA laboratory was not in compliance with NVLAP, based on a cursory review of count sheet and other limited data without the in-depth examination detailed above, is therefore invalid and cannot be used to question EPA’s analytical results.

EPA chose NVLAP-accredited laboratories for the El Dorado Hills assessment as a minimum quality requirement. For supplemental quality assurance, the laboratories were subjected to on-site audits performed by EPA’s Quality Assurance Technical Support group, and both laboratories were sent performance evaluation samples prior to analysis of the El Dorado samples. In addition, the laboratory conducting the air sample analysis was sent double blind performance evaluation samples during the sampling event. In all cases, the laboratories successfully identified the amounts and types of asbestos present on the blind samples within acceptable limits. Further, the El Dorado Hills air and soil data were validated by a third party in accordance with standard EPA quality assurance

¹⁷S.J. Ring (1981). Identification of Amphibole Fibers, Including Asbestos, Using Common Electron Diffraction Patterns. In Russell P.A. and Hutchings A.E. (Eds), Electron Microscopy and X-ray Applications to Environmental and Occupational Health Analysis, Vol. 2:175-198, Ann Arbor Science Publ., Inc.

procedures and were found to be acceptable for all uses.

R. J. Lee Finding #3: “The Soil Samples do not Demonstrate the Presence of Amphibole Asbestiform Minerals.”

The R. J. Lee Report states that the actinolite asbestos fibers identified in the El Dorado Hills soil samples contain too much aluminum to be asbestiform and that the extinction angles of the fibers indicate that they are non-fibrous cleavage fragments. The R.J. Lee Group’s analysis of 23 split soil samples from EPA’s October 2004 sampling event found no asbestos in the samples.

EPA Response

Aluminum - The R. J. Lee Report states that the aluminum content of the fibers in the soil samples was too high to be asbestiform actinolite and that it was indicative of non-asbestiform actinolite and another amphibole, hornblende, which contains approximately 10-20% by weight Al_2O_3 (5.3-10.6% by weight aluminum). Both the laboratory performing EPA’s El Dorado soil sample analysis and the laboratory which analyzed the EPA air samples noted significant quantities of hornblende in the samples, but did not count or report those particles as asbestos. Please see the EPA response to Finding #1 for a further discussion of the aluminum issue.

Extinction Angles - The extinction angle of a fiber evaluated by polarized light microscopy is one of many criteria used to identify mineralogical composition. The extinction angle for amphibole asbestos fibers is the difference in degrees between the long axis of the fiber and the angle at which the fiber optically disappears (the polarization direction where the light passing through it becomes “extinct”) when the fiber is rotated under a polarized light microscope. The R.J. Lee Report states that amphibole asbestos fibers have a zero-degree extinction angle and that non-asbestos cleavage fragments have non-zero extinction angles. Therefore, because the EPA soil sample analysis reported extinction angles which, according to the R.J. Lee Group, averaged 12°, the report alleges EPA incorrectly identified cleavage fragments as asbestos fibers.

The R.J. Lee Report’s conclusion regarding extinction angles is contradicted by the National Institute of Standards and Technology (NIST) and the major analytical methods used for analysis of asbestos in soil and bulk samples. NIST certifies and provides Standard Reference Materials (SRM) for laboratory instrument calibration and laboratory accuracy measurement. The NIST Tremolite/Actinolite SRM 1867A is a special set of three samples certified by NIST to be of ultra-high purity tremolite, actinolite, and anthophyllite asbestos and is considered the “gold standard” for asbestos analytical laboratories. The material is rigorously characterized and is accompanied by a six-page document that describes the properties of each sample. It is required that all analytical laboratories accredited by NIST/NVLAP have the material in their possession and that they use it to calibrate their operations and to test their analysts. The NIST SRM

1867A certificate which accompanies the samples of tremolite and actinolite states that the reference tremolite can have an extinction angle of up to $16.6 \pm 0.3^\circ$ and that the actinolite can have an extinction angle of up to $15.9 \pm 0.2^\circ$. When the EPA laboratory processed the NIST actinolite standard in the manner of the El Dorado Hills soil samples, the extinction angles of the fibers in the processed standard sample were consistent with allowed maximum extinction angles for tremolite/actinolite asbestos ($\sim 10^\circ$ to 20°) and the extinction angles of the fibers seen in the EPA soil samples.¹⁸

Further, the laboratory methods of EPA, NIOSH, and other agencies for analysis of asbestos in bulk material all state that tremolite-actinolite asbestos fibers may have zero (parallel) or *non-zero* (inclined or oblique) extinction angles. EPA Method 600/R-93/116¹⁹, the standard method used by all NIST/NVLAP accredited laboratories to test building materials for the presence of asbestos, states in Table 2-2, Optical Properties of Asbestos Fibers, that tremolite-actinolite asbestos has extinction “parallel and oblique (up to 21°).” NIOSH Method 9002²⁰, the method used for analysis of the El Dorado Hills soil samples, states directly that actinolite and tremolite fibers exhibiting inclined extinction are to be considered asbestos. The method further states that “If anisotropic fibers are found (during PLM analysis), rotate the stage to determine the angle of extinction. Except for tremolite-actinolite asbestos which has oblique extinction at $10\text{--}20^\circ$, the other forms of asbestos exhibit parallel extinction... Tremolite may show both parallel and oblique extinction.”²¹

R.J. Lee Finding #4: “The ISO 10312 Analytical Method can not Distinguish Between Asbestos Fibers and Non-Asbestos Cleavage Fragments.”

The R.J. Lee Report states that the ISO 10312 method contains the disclaimer that “The method cannot discriminate between individual fibers of asbestos and non-asbestos analogues of the same amphibole material,” and, therefore, EPA inflated the asbestos air concentrations by counting “cleavage fragments.”

EPA Response

The ISO 10312 method cannot differentiate between fibers and cleavage fragments with

¹⁸M. Bailey (2006). Identification of Asbestiform Tremolite/Actinolite. Naturally Occurring Asbestos Workgroup Meeting Presentation.

¹⁹USEPA (U.S. Environmental Protection Agency) (1993). Method for the Determination of Asbestos in Bulk Building Materials. EPA Method 600/R-93/116.

²⁰NIOSH (National Institute for Occupational Safety and Health) (1992). Asbestos (Bulk) by PLM.. Method 9002 (Issue 2).

²¹NIOSH (National Institute for Occupational Safety and Health) (1992). Asbestos (Bulk) by PLM.. Method 9002 (Issue 2). Qualitative Assessment, Item c, page 4.

the same dimensions and chemical composition. No routine analytical method has a protocol for distinguishing fibers from cleavage fragments on an individual particle basis. Additionally, from a health standpoint, there is no evidence that supports making the distinction.

Cleavage fragment is a geologic term which refers to structures that form when non-fibrous forms of asbestos minerals split along crystallographic planes, as opposed to asbestos fibers which form from crystalline growth. The R.J. Lee Report maintains that there is a toxicological difference between asbestos structures which formed as fiber crystals and fibers which formed by cleavage plane separation. Page 3 of the R.J. Lee Report states that cleavage fragments are “not known to produce asbestos-like disease.” **It is the position of EPA, the U.S. Centers for Disease Control and Prevention, Agency for Toxic Substances and Disease Registry (ATSDR) and National Institute for Occupational Safety and Health (NIOSH), and the American Thoracic Society, among others, that microscopic structures of amphibole and serpentine minerals that are asbestiform and meet the size definition of PCM fibers, should be counted as asbestos, regardless of the manner by which they were formed.** There are four reasons why the health agencies have taken this position: (1) The epidemiologic and health studies underlying EPA, and California EPA, cancer risk assessment methods were based on exposures to both cleavage fragments and fibers, but were unable to distinguish between the two, (2) The most recent panel of experts to review asbestos risk assessment methods, the 2003 Peer Consultation Panel convened by EPA, concluded that “it is prudent at this time to conclude equivalent potency [of cleavage fragments and fibers] for cancer,”²² (3) No well-designed animal or human epidemiological studies have been conducted to date to test the hypothesis that cleavage fragments with the same dimensions of a fiber are benign, or that the human body makes any distinction, and studies that purport to show that cleavage fragments are benign are questioned by many asbestos health experts,²³ (4) There are no routine air analytical methods, including those used by EPA, NIOSH, the Mine Safety and Health Administration (MSHA), the American Society for Testing and Materials (ASTM), and the ISO which differentiate between cleavage fragments and crystalline fibers.

²²USEPA (U.S. Environmental Protection Agency) (2003). Report on the Peer Consultation Workshop to Discuss a Proposed Protocol to Assess Asbestos-Related Risk, Final Report. Office of Solid Waste and Emergency Response, Washington D.C. Page viii.

²³Both Addison (Addison J, Davies LST. 1990. Analysis of amphibole asbestos in chrysotile and other minerals. Ann Occ Hyg, Apr;34(2):159-75) and members of the U.S. EPA 2003 Peer Consultation panel raised concerns about interpretation of the Davis study (Davis JM, McIntosh C, Miller BG, Niven K. 1991. Variations in the carcinogenicity of tremolite dust samples of differing morphology. Ann NY Acad Sci, Dec;643:473-90), which attempted to compare the toxicity of asbestos fibers and cleavage fragments. These concerns reflected the lack of peer review, use of intra peritoneal injection instead of inhalation exposure, significance of mesotheliomas caused by structures reported as cleavage fragments, purity of the cleavage fragment samples and issues related to fiber dimensions.

In terms of epidemiological data and health outcomes, the cleavage fragment argument is without merit. For the purposes of public health assessment and protection, EPA makes no distinction between fibers and cleavage fragments of comparable chemical composition, size, and shape.

There are no recognized analytical protocols, including those used by EPA, NIOSH, MSHA, ASTM, and ISO, which include criteria to differentiate between cleavage fragments and crystalline fibers. All these methods require that structures which meet their definition of the specific counting rules for an asbestos fiber be counted. The requirements are based on the fact that, in the words of an expert from the United States Geological Survey, “At a microscopic level, distinguishing between these forms on single [asbestos] particles, can be extremely difficult to impossible.”²⁴ As noted above, R.J. Lee made a very similar claim with regard to cleavage fragments as the expert witness for W.R. Grace in the Libby, Montana, Superfund cost recovery litigation. The EPA analytical experts who reviewed the R.J. Lee Group’s testing methodology related to the Libby site found that the R.J. Lee laboratory could not demonstrate any reliable criteria with which to distinguish, at the microscopic level, asbestos cleavage fragments from asbestos fibers of the same size, shape, and composition. The Ninth Circuit Court of Appeals recognized the competing scientific arguments but found that EPA’s position was consistent with the record of evidence and accepted scientific principles.²⁵

R.J. Lee Finding #5: “Applying the Latest Science and Definitional Techniques, the El Dorado Hills Study Shows no Significant Exposure to the Type of Amphibole Asbestos Fiber Connected To Health Risk.”

The R. J. Lee Report claims that the latest science for measuring the risk posed by asbestos is the Berman-Crump Asbestos Risk Assessment Protocol (“Berman-Crump”) which proposes that amphibole asbestos fibers which are more than 10 microns long and less than 0.5 microns wide (protocol fibers) are the most toxic. Of the 2,386 fibers which the R. J. Lee Report states the EPA laboratory identified, the R.J. Lee Report concludes that only 7 fibers meet the “Berman-Crump” definition. Therefore, the R.J. Lee Group maintains that EPA has overstated the risk from exposure to asbestos fibers in El Dorado Hills.

EPA Response

The “Berman-Crump” protocol that the R.J. Lee Report references is in fact a draft EPA method. EPA had the method reviewed by a peer consultation panel in 2003. The panel made a number of important recommendations that must be addressed before the method can be used for EPA risk assessments. A number of important revisions have been made

²⁴G.P. Meeker, USGS, (2002). Review of Expert Report of R.J. Lee.

²⁵U.S. v. W.R. Grace, 429 F.3d at 1245.

to the draft method since 2003, but at this time the method has not been independently peer reviewed. It will not be adopted by EPA as a risk assessment tool unless and until it passes rigorous internal and external peer review.

The expert peer panel has recommended that the fiber size for the draft EPA risk assessment method be adjusted to include fibers greater than 5 microns in length and up to 1.5 microns in width.²⁶ The change is designed to account for lung deposition of fibers that results when fibers are inhaled through the mouth, and not filtered by the nasal passages. The broadening of the fiber definition to include inhalation by “mouth breathers” is especially relevant to the El Dorado Hills data. Our investigation measured personal asbestos exposures of individuals participating in sports activities, where physical exertion would likely increase breathing through the mouth. **The PCME fibers counted in the EPA air samples are actually consistent with the latest science of EPA, as reflected in the recommendations of the peer consultation panel.** In addition, the EPA peer consultation expert panel recommended that cleavage fragments be treated as any other asbestos fiber of the same morphology and chemical composition.²⁷

EPA Region 9 focused on obtaining an accurate count of PCME structures, consistent with our risk assessment protocols and those of Cal/EPA and other health agencies. The counting rules which EPA set for the laboratory were designed to stop counting when a statistically-significant number of PCME fibers were detected. By concentrating on PCME structures, other fiber size classifications may not have been counted to statistical significance. This may have resulted in under counts of other fiber sizes (e.g. the “Berman Crump” protocol fibers referred to in the R. J. Lee Report). **EPA Region 9's study counted PCME structures so that the data could be directly compared to human health epidemiological studies.** These epidemiological studies form the basis for risk assessment models currently used by EPA, Cal/EPA and other federal agencies and international organizations.

R. J. Lee Report Peer Reviews

The R. J. Lee Report was reviewed by three individuals, although research of one of the individuals was extensively quoted in the report and therefore the independence of the reviewer is debatable. The three reviewers generally agree with the conclusions of the R. J. Lee Report regarding aluminum content, fiber chemistry, cleavage fragments, and extinction angles.

Both the R. J. Lee Report and one of the reviewers support use of the original “Berman-

²⁶USEPA (U.S. Environmental Protection Agency) (2003). Report on the Peer Consultation Workshop to Discuss a Proposed Protocol to Assess Asbestos-Related Risk, Final Report. Office of Solid Waste and Emergency Response, Washington D.C. Page 5-5.

²⁷Ibid, page 5-1.

Crump” protocol and calculate a “Berman-Crump” fiber air concentration of 0.0002 fibers/cubic centimeter, using the EPA fibers which they assert meet the “Berman-Crump” definition. The peer reviewer then compares that concentration with an ambient concentration of 0.0008 fibers/milliliter measured in New York City, and states that the “Berman-Crump” value in El Dorado Hills is extremely low. This comparison is flawed for at least two reasons. Significantly, the New York City numbers are based on fibers counted against a totally different size classification (essentially comparing apples to oranges), but **the reviewer also fails to recognize that a concentration of 0.0002 f/cc translates in the protocol to an increased cancer risk of 1 in 1,000 exposed individuals.** This number is disturbingly high and is outside the acceptable cancer risk ranges of EPA, Cal/EPA, and most other state and federal health agencies.

Conclusions

EPA Region 9 has carefully reviewed the R. J. Lee Report and believes that it makes largely unsupported and incorrect conclusions about the EPA Region 9 El Dorado Hills Naturally Occurring Asbestos Exposure Assessment. EPA Region 9 has asked the United States Geological Survey (USGS) to conduct an independent study of the El Dorado County area to address several mineralogical questions raised by the R. J. Lee Report. The USGS study will use sophisticated analytical techniques (such as electron probe micro analysis) to more completely characterize the naturally occurring asbestos in terms of mineral identification and particle morphology.

All of the EPA Region 9 work in El Dorado Hills was, and continues to be, consistent with the EPA’s standard operating and quality control procedures for asbestos work throughout the country.

Exhibit 162

Johnson & Johnson
BABY PRODUCTS COMPANY

for Talc testing
Molnar c J. Bandier
SLU.

October 4, 1984

SKILLMAN, N. J. 08558

TO: B. Semple, M.D.

SUBJECT: Evaluation Program for Talc

The following tests are run on all biweekly composite samples from Windsor Minerals and on yearly International Talc Audit samples.

- 1) X-ray diffraction for qualitative mineralogical composition.
- 2) Slow scanning x-ray diffraction for amphibole minerals (CTFAJ4-1).
- 3) Presence of free crystalline silica (quartz) by x-ray diffraction (CTFAJ6-1).

In addition, a quarterly composite is made from the biweekly Windsor Minerals samples and analyzed by Transmission Electron Microscopy (BPC Test Method 7024) for serpentine minerals.

James A. Molnar
James A. Molnar

JAM:rp
0522R

Exhibit 163

Page 1

1 SUPERIOR COURT OF NEW JERSEY
2 LAW DIVISION: MIDDLESEX COUNTY
3 DOCKET NO. MID-1809-17AS
4 APPELLATE DOCKET NO. _____

5 DOUGLAS AND ROSLYN BARDEN,)
6 v.) TRIAL
7 BRENNTAG NORTH AMERICA, et al.,) (VOLUME 1 OF 2)
8 Defendants.)
9 DAVID CHARLES ETHERIDGE AND)
10 DARLENE PASTORE ETHERIDGE,)
11 Plaintiffs,)
12 v.)
13 BRENNTAG NORTH AMERICA, et al.,)
14 Defendants.) MID-L-7049-16AS
15 D'ANGELA MCNEILL-GEORGE,)
16 Plaintiff,)
17 v.)
18 BRENNTAG NORTH AMERICA, et al.,)
19 Defendants.) MID-L-6040-17AS
20 WILLIAM AND ELIZABETH RONNING,)
21 Plaintiffs,)
22 v.)
23 BRENNTAG NORTH AMERICA, et al.,)
24 Defendants.

	Page 2	Page 4
1	Place: Middlesex County Courthouse 56 Paterson Street New Brunswick, New Jersey 08903	1 INDEX
2		2
3	Date: Wednesday, January 29, 2020 9:05 a.m. (Volume 1 of 2) (Pages 1 - 200)	3 WITNESS PAGE
4		4 FOR THE DEFENDANTS:
5		5
6		6 MATTHEW SANCHEZ
7		7 CROSS-EXAMINATION BY MR. PANATIER 7,194
8		8 REDIRECT EXAMINATION BY MR. DUBIN 136,212
9	BEFORE:	9
10	HON. ANA C. VISCOMI, J.S.C. and JURY	10
11		11
12		12
13		13
14		14
15	TRANSCRIPT ORDERED BY:	14
16	MOSHE MAIMON, ESQ. LEVY KONIGSBERG	15
17		16
18		17
19		18
20	ANDREA F. NOCKS, CCR, CRR PRIORITY ONE 290 West Mount Pleasant Avenue	19
21	Livingston, New Jersey 07039 (718) 983-1234	20
22	E-mail: p1steno@veritext.com	21
23		22
24		23
25		24
		25
	Page 3	Page 5
1	APPEARANCES:	1 INDEX
2	CHRISTOPHER PLACITELLA, ESQ COHEN, PLACITELLA & ROTH	2 EXHIBITS
3	127 Maple Avenue Red Bank, New Jersey 07701	3 NO. ID EVD
4	-and-	4 S-4 19
5	MOSHE MAIMON, ESQ	5 S-5 84
6	LEVY KONIGSBERG 800 3rd Avenue	5 S-6 110
7	11th Floor New York, New York 10022	5 S-7 173
8	-and-	6 Plaintiff's Exhibit 3695-247 103
9	CHRIS J PANATIER, ESQ SIMON GREENSTONE PANATIER 1201 Elm Street	7 Plaintiff's Exhibit 3695-249 125
10	Suite 3400 Dallas, Texas 75270	8 Plaintiff's Exhibit 3695-252 103
11	Attorneys for Plaintiffs, Douglas and Roslyn Barden,	9 Plaintiff's Exhibit 3695-253 103
12	David Charles Etheridge and Darlene Pastore Etheridge, D'Angela McNeill-George, William and Elizabeth Ronning	10
13		11
14	ALLISON M BROWN, ESQ SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP	12
15	4 Times Square New York, New York 10036	13
16	-and-	14
17	ORRICK	15
18	MORTON DUBIN, ESQ KEVIN HYNES, ESQ	16
19	51 West 52nd Street New York, New York 10019	17
20	Attorneys for Defendants, Johnson & Johnson, and Johnson & Johnson Consumer, Inc	18
21		19
22		20
23		21
24		22
25		23
		24
		25

	Page 6	Page 8 1 and nothing that was on these boards was inaccurate? 2 A. I'm sorry? 3 Q. Nothing on these boards failed to 4 report exactly what was in the documents that 5 they're talking about, correct? 6 A. I believe that's correct. 7 Q. Okay. So, you know, many times you 8 were asked this question, does that say asbestos. 9 Now, let's just take, for instance, 10 tremolite asbestos. Before you have tremolite 11 asbestos you have to have tremolite, right? 12 A. Well, yes, tremolite asbestos would 13 also be, the correct mineral name for the 14 identification would also have tremolite part of it. 15 Q. You have to have the actual mineral 16 tremolite present; true? 17 A. That's true. 18 Q. And so same question for something 19 like anthophyllite; if you have anthophyllite 20 asbestos, you have to have anthophyllite, the 21 mineral, present, correct? 22 A. Correct. It would be the asbestosiform 23 variety of anthophyllite, yes. 24 Q. And if we go to some of the earliest 25 studies that Johnson & Johnson had, and you're
	Page 7	Page 9 1 So, members of the jury, you may 2 recall yesterday we commenced with the defendants' 3 portion of this case and their expert witness, 4 Matthew Sanchez, is testifying now on 5 cross-examination. 6 Mr. Panatier, you may continue. 7 MR. PANATIER: Okay. Thank you, your 8 Honor. 9 THE COURT: Just a reminder, you were 10 here yesterday and placed under oath. We are not 11 going to re-administer the oath, but just a reminder 12 you are under oath. 13 THE WITNESS: Understand. 14 THE COURT: There is a microphone 15 that is placed there now that will amplify your 16 voice. 17 THE WITNESS: Thank you. 18 M A T T H E W S A N C H E Z, previously sworn. 19 CONTINUED CROSS-EXAMINATION BY MR. PANATIER: 20 Q. You have a personal speaker now. 21 So yesterday you and Mr. Dubin spent 22 some time going through these boards. I'm sure you 23 recall all that? 24 A. I do. 25 Q. So to make it very clear, nothing,

<p style="text-align: right;">Page 10</p> <p>1 correct?</p> <p>2 A. I don't understand that. They were 3 characterizing what they saw, dominant in the talc. 4 Talc was the dominant mineral. Then you're going to 5 be chlorite and the dolomites and carbonates would 6 be the next most frequent, and then on some of the 7 reports there was a small amount of tremolite they 8 observed.</p> <p>9 Q. In fact, tremolite came up quite a 10 bit in those reports, correct?</p> <p>11 A. Well, many of those are testing of 12 the same samples, so yes, you wouldn't expect a 13 repeat finding if it was actually there.</p> <p>14 Q. You're not saying these are repeat 15 samples, are you?</p> <p>16 A. If you look at, many of those tests 17 are of Italian 1 and Italian 2 that are repeated 18 over and over again, so a lot of those are just 19 testing of the same material for different purposes.</p> <p>20 Q. Italian 1 and Italian 2 were two 21 different grades that were coming out of the same 22 mine, correct?</p> <p>23 A. That's correct.</p> <p>24 Q. All right. So you guys spent some 25 time going through the boards and looking at the</p>	<p style="text-align: right;">Page 12</p> <p>1 Q. He says they were hardly fibrous, 2 right?</p> <p>3 A. That is the word he uses, yes.</p> <p>4 Q. Now, when you dig into the documents, 5 have you looked at Dr. Pooley's testimony by -- that 6 was, I believe, Mr. Bicks, who is Mr. Dubin's 7 partner, was present at the deposition.</p> <p>8 Have they shown you this testimony 9 about this section?</p> <p>10 A. I don't believe so.</p> <p>11 Q. Let me show it to you and ask you 12 some questions.</p> <p>13 MR. DUBIN: Your Honor, I would 14 object.</p> <p>15 THE COURT: Sure.</p> <p>16 (Sidebar.)</p> <p>17 MR. DUBIN: I didn't understand he 18 was intending to cross-examine this witness with the 19 portion of the transcript they're not introducing 20 into evidence that he says he hasn't reviewed. I 21 wasn't even allowed to ask him about things like the 22 Blount transcript that he has reviewed and 23 considered for purposes of his opinion.</p> <p>24 It's not part of his opinion in the 25 case, nor litigation deposition of Dr. Pooley, what</p>
<p style="text-align: right;">Page 11</p> <p>1 documents and I'd like to do a little bit of that, 2 too, to sort of give us the full picture on the 3 story. And I think you said yesterday, you said you 4 really have to dig into the documents and learn what 5 you can, right?</p> <p>6 A. As much as possible, yes.</p> <p>7 Q. So I'd like to do that a little bit.</p> <p>8 The first thing I want to do is show 9 you, this is the Fred Pooley 1972 Italian study that 10 he did, and you guys talked about that, correct?</p> <p>11 A. We did.</p> <p>12 Q. It's like 150 pages long. But if you 13 go right to the conclusions, it says this: "The 14 talc specimens were, however, plate-like in 15 appearance with varying quantities of lath-like 16 particles coupled with fibers which were textile in 17 appearance.</p> <p>18 "Both lath and textile types of 19 particles were not composed of minerals associated 20 with the commercial asbestos industry. Particles 21 formed from amphibole mineral found at the mine were 22 hardly fibrous in character, the majority of the 23 tremolite breaking to give compact particles."</p> <p>24 Right? Did I read that correctly?</p> <p>25 A. You did.</p>	<p style="text-align: right;">Page 13</p> <p>1 I understand your Honor's guidelines to be part of 2 the record for purposes of punitive damages.</p> <p>3 MR. PANATIER: The Blount situation 4 was one of what the disclosure was and what the four 5 corners of the report was. That was a scope issue 6 having to do with notice. This is not. This is 7 what have you reviewed when he commented on this. 8 And Dr. Pooley -- I can actually lay a foundation. 9 I can ask him --</p> <p>10 THE COURT: Let him just complete, 11 let him finish --</p> <p>12 MR. DUBIN: Okay.</p> <p>13 THE COURT: -- what he was saying.</p> <p>14 MR. PANATIER: I can lay a 15 foundation. I can ask him if Dr. Pooley clarified 16 what he meant by hardly fibrous. Would you like to 17 see it? I'm happy to do that. If he says no, fine.</p> <p>18 MR. DUBIN: That is a gamesmanship 19 technique to ask that in front of the jury to try to 20 get something in that's not admissible. He also 21 looks like he's going to hand him a page of what was 22 a full day deposition which the witness would need 23 an opportunity to have reviewed in full before 24 answering questions.</p> <p>25 MR. PANATIER: An expert can consider</p>

<p style="text-align: right;">Page 14</p> <p>1 matters that are hearsay, that are inadmissible and 2 he can evaluate it. If he believes he needs more 3 context, it's three questions. And if he says I 4 need more context, he can say he needs more context. 5 But he's not gonna. And this came in in Phase I. I 6 crossed John Hopkins with it.</p> <p>7 THE COURT: Okay. So during his 8 direct you went through plaintiffs' boards and went 9 through documents --</p> <p>10 MR. DUBIN: Correct.</p> <p>11 THE COURT: -- as to whether or not 12 it was asbestosiform, non-asbestosiform, how it was 13 categorized. Was this document one that plaintiff 14 was --</p> <p>15 MR. PANATIER: This is.</p> <p>16 THE COURT: I'm sorry, the defendants 17 went through on direct?</p> <p>18 MR. PANATIER: This document is.</p> <p>19 MR. DUBIN: I did not go through -- 20 this is a multipage deposition. We're talking about 21 historical documents what they actually said. He's 22 questioning him now about what the historical 23 documents says which goes to whatever Johnson & 24 Johnson's knowledge was at the time. If this 25 witness -- we're now getting into litigation</p>	<p style="text-align: right;">Page 16</p> <p>1 MR. DUBIN: Then -- 2 THE COURT: You will have it before 3 redirect. Have someone work on that. 4 MR. PANATIER: We will. 5 (Sidebar ends.) 6 THE COURT: Proceed.</p> <p>7 BY MR. PANATIER:</p> <p>8 Q. All right. So I'm going to hand you 9 an excerpt from Dr. Pooley's deposition and do you 10 see at the top it says, "Fred Pooley, Ph.D."?</p> <p>11 A. It does.</p> <p>12 Q. That's the same Pooley that authored 13 this report and the Pooley that you talked about at 14 length?</p> <p>15 A. Yes.</p> <p>16 Q. Right? Okay.</p> <p>17 If you go to the second page there's 18 a reference, there's some highlights there and 19 there's a reference to Mr. Bicks, and the question 20 you're asked, the question you're asked is, 21 "Mr. Bicks has inadequately quoted this report. 22 Particles formed from the amphibole mineral found at 23 the mine were hardly fibrous."</p> <p>24 And you and I just read that, right?</p> <p>25 A. That's correct.</p>
<p style="text-align: right;">Page 15</p> <p>1 depositions.</p> <p>2 First of all, the witness would need 3 an opportunity to review the deposition and comment 4 on whether the plaintiffs would put that into 5 evidence if they wish, but not with this witness. 6 Otherwise, I don't see why I can't ask him about 7 things that Dr. Blount said about her findings.</p> <p>8 THE COURT: Well, he was limited to 9 the four corners of his report. Dr. Blount was not 10 in the four corners of his report. Here this is a 11 document, the underlying document which you went 12 through with him on direct.</p> <p>13 This is permissible cross-examination 14 and you'll have the opportunity for redirect.</p> <p>15 MR. DUBIN: I would ask the witness 16 be given a full copy of the transcript and enough 17 time to read the transcript before being asked the 18 questions about two lines from the transcript. I 19 think that is only fair.</p> <p>20 THE COURT: I think that you could 21 find if counsel is mischaracterizing those sections 22 you have the opportunity on redirect.</p> <p>23 MR. DUBIN: Do you have the full 24 transcript?</p> <p>25 MR. PANATIER: I don't have --</p>	<p style="text-align: right;">Page 17</p> <p>1 Q. Dr. Pooley said yeah.</p> <p>2 Next question, "The majority broke to 3 give compact particles. They got too small. 4 Doesn't mean all of them did, does it?"</p> <p>5 And Dr. Pooley, he has to ask it 6 again, "Doesn't mean all of them did, does it?"</p> <p>7 And Dr. Pooley says nope.</p> <p>8 The next question was, "So he didn't 9 quote it here, but you found tremolite that was 10 asbestosiform that didn't break apart, didn't you?"</p> <p>11 And he said, "Yes, a few particles.</p> <p>12 Yes."</p> <p>13 Correct?</p> <p>14 A. You read that correctly.</p> <p>15 Q. Okay. Dr. Pooley did find 16 asbestosiform tremolite, correct?</p> <p>17 A. No. That is not what he says in his 18 report and this question is confusing.</p> <p>19 Q. Well, we can look at it with our 20 eyes. We just saw this section here.</p> <p>21 Oops, can I go to the Elmo, please?</p> <p>22 Thank you.</p> <p>23 We just saw this section here, 24 "particles formed from the amphibole mineral found 25 at the mine were hardly fibrous," right?</p>

<p>1 A. Yes.</p> <p>2 Q. And the lawyer there asks this</p> <p>3 question, "Doesn't mean all of them did, does it?</p> <p>4 "Nope.</p> <p>5 "So he didn't quote it here, but you</p> <p>6 found tremolite that was asbestiform that didn't</p> <p>7 break apart, didn't you?</p> <p>8 "ANSWER: Yes, a few particles.</p> <p>9 Yes."</p> <p>10 Did I read that right?</p> <p>11 A. You did.</p> <p>12 Q. When you're talking about TEM with</p> <p>13 the electron microscope, if you see just a few</p> <p>14 particles in this tiny, tiny, tiny little bit,</p> <p>15 depending on the dilution and all of that, you could</p> <p>16 be talking about thousands to millions to billions</p> <p>17 of fibers, depending; correct?</p> <p>18 A. I don't know if you'd ever get to</p> <p>19 billions on only a few, but again, it would depend</p> <p>20 on the math on where the concentration would go.</p> <p>21 THE COURT: Counsel, for the record,</p> <p>22 could you identify that Pooley report by exhibit</p> <p>23 number?</p> <p>24 MR. PANATIER: I'm sorry. We didn't</p> <p>25 have it marked, but we would mark it as, I think we</p>	<p>Page 18</p> <p>1 to --</p> <p>2 MR. DUBIN: I'm sorry, which</p> <p>3 document?</p> <p>4 MR. PANATIER: July 23rd, '71. Do</p> <p>5 you guys have it marked?</p> <p>6 MR. DUBIN: I'm sure we did.</p> <p>7 MR. HYNES: That's 2386.</p> <p>8 THE COURT: Thank you very much.</p> <p>9 MR. PANATIER: This is 2386.</p> <p>10 BY MR. PANATIER:</p> <p>11 Q. All right. July 23rd, 1971. They're</p> <p>12 looking at the baby powder talc, correct?</p> <p>13 A. One of the samples, yes.</p> <p>14 Q. Right.</p> <p>15 And they said, "Trace amounts of a</p> <p>16 mineral with a lattice spacing of 3.05 Å was noted</p> <p>17 in the head and tail samples," correct?</p> <p>18 A. Correct.</p> <p>19 Q. They don't even identify what</p> <p>20 amphibole that would be, correct?</p> <p>21 A. That's not what I said. May I go</p> <p>22 further?</p> <p>23 Q. Sure, go ahead.</p> <p>24 A. Okay. Thank you.</p> <p>25 When you have a mineral and you do</p>
<p>1 have an S-4 --</p> <p>2 MR. DUBIN: Defense 7038.</p> <p>3 THE COURT: Defense 7038?</p> <p>4 MR. DUBIN: I believe so.</p> <p>5 MR. PANATIER: The Pooley report?</p> <p>6 THE COURT: Yes.</p> <p>7 MR. PANATIER: We would mark the</p> <p>8 deposition excerpt just as S-4 for identification.</p> <p>9 THE COURT: Thank you.</p> <p>10 (S-4 was marked for identification.)</p> <p>11 BY MR. PANATIER:</p> <p>12 Q. You also talked about Colorado School</p> <p>13 of Mines, some of their findings, right?</p> <p>14 A. I did.</p> <p>15 Q. And some of the things that I had put</p> <p>16 on our boards?</p> <p>17 A. That's correct.</p> <p>18 Q. You talked about this document from</p> <p>19 July 23rd, 1973?</p> <p>20 THE COURT: For the record, what was</p> <p>21 that marked as?</p> <p>22 MR. PANATIER: I don't remember.</p> <p>23 They didn't have -- they didn't have the exhibit</p> <p>24 numbers up that I saw.</p> <p>25 THE COURT: You're going to have</p>	<p>Page 19</p> <p>Page 21</p> <p>1 your X-ray diffraction on it, we showed you the one,</p> <p>2 we showed the jury the one graph we had all those</p> <p>3 different peaks. So every mineral will have a set</p> <p>4 of peaks. Some of those peaks will be unique to</p> <p>5 that mineral, some of the peaks will not be unique</p> <p>6 to that mineral.</p> <p>7 So the specific peak that would</p> <p>8 correspond to that 3 Angstrom, that 305 Å, as they</p> <p>9 referred to in the document, that is not a unique</p> <p>10 peak for an amphibole. That could be any number of</p> <p>11 materials. The unique peak for amphiboles are at</p> <p>12 different positions which they don't make any</p> <p>13 mention of.</p> <p>14 So you assume they weren't seeing the</p> <p>15 unique features of the amphibole, but they had some</p> <p>16 peak that they couldn't match up. An amphibole is</p> <p>17 only one of many possibilities that could match for</p> <p>18 that peak.</p> <p>19 Q. Okay. Well, I'm going to show you</p> <p>20 Plaintiffs' Exhibit 3695-25. This is eight days</p> <p>21 later. August 3rd.</p> <p>22 Do you see that?</p> <p>23 A. I do.</p> <p>24 Q. Do you see where they say</p> <p>25 anthophyllite, and they say 3.05 Å?</p>

<p style="text-align: right;">Page 22</p> <p>1 A. That's correct. That is a, that is 2 one of many peaks for anthophyllite. 3 Q. Okay. So they identified in the 4 Vermont 66, 305 A, eight days later, they identified 5 that as anthophyllite, correct? 6 A. No. That's incorrect. They're 7 simply reporting, so if you pull up the -- may I 8 explain further? I'm sorry. 9 Q. I'm just going to ask you, sir, do 10 they identify eight days later anthophyllite as 11 having major anthophyllite lines at 8.5 A and 3.05 12 A? 13 A. That is correct. Anthophyllite would 14 have -- those are two of the many reflections for 15 anthophyllite that they identified there. 16 Q. Okay. Let's look at, this is 17 Plaintiffs' Exhibit 2808, because I want to now get 18 the full story. You said you had to dig into the 19 documents, so let's do that a little bit. 20 This is June 30, 1971. And you can 21 see here, Colorado School of Mines. And they report 22 that "Based upon X-ray diffraction and microscopical 23 analyses of the Vermont finished product plant run 24 sample 344 L" -- now, you know 344 L was a 25 production sample of Johnson's Baby Powder, correct?</p>	<p style="text-align: right;">Page 24</p> <p>1 MR. DUBIN: I am just asking -- 2 THE COURT: Excuse me, can you 3 provide a copy to the witness? 4 MR. PANATIER: Your Honor, I pulled 5 these straight out in response to cross. They have 6 been provided to counsel. 7 THE COURT: Does anyone have a copy 8 for the witness? 9 MR. PANATIER: I'll let the witness 10 look at it first if he wants to look at it. 11 THE COURT: Thank you. 12 MR. PANATIER: Here you go. 13 (Handing.) 14 MR. DUBIN: What is the exhibit 15 number? 16 MR. PANATIER: That was 2808. 17 BY MR. PANATIER: 18 Q. That's their methodology that they go 19 through and they detail, correct? 20 A. Yes, they do talk about their 21 methodology here. 22 Q. This next document, I think, might 23 help us understand whether they were looking at 24 separate samples. If you want to look at this. 25 This is Plaintiffs' Exhibit 2378. I'll show it to</p>
<p style="text-align: right;">Page 23</p> <p>1 A. I believe it was. 2 Q. -- "and six monthly Vermont finished 3 product samples, only very trace amounts of 4 tremolite actinolite were identified." Right? 5 A. That's correct. 6 Q. They looked at seven things, they 7 looked at one 344 L, which was baby powder, and then 8 they looked at the finished product samples for six 9 other monthly Vermont runs of the product, correct? 10 A. I don't know the number here based on 11 what you're showing me. 12 Q. Right there it says six. 13 A. I apologize. 14 Q. Okay. 15 A. Thank you. 16 Q. No problem. 17 A. I'm sorry, I need to go back, I don't 18 know the number of samples. They're just saying 19 samples that represented six monthly runs. I just 20 want to make sure we're talking about the correct 21 number of samples. 22 Q. That's fine. They tell us. 23 MR. DUBIN: Do you have a copy? 24 MR. PANATIER: I'm pulling these 25 straight out of the admitted exhibits that we've --</p>	<p style="text-align: right;">Page 25</p> <p>1 you. July 7, 1971. 2 Does this help right here? 3 A. Let me finish this document. 4 Q. Okay. 5 A. I'll go to the next one. Thank you. 6 MS. BROWN: Your Honor, we do have 7 extra copies of what counsel's asking about that we 8 can give to the witness. 9 THE COURT: Thank you very much. 10 MS. BROWN: Chris, this is the first 11 one. 12 BY MR. PANATIER: 13 Q. Now we're looking at this one, and 14 this one is from July 7, 1971, right? 15 A. Yes. This one is. 16 Q. Do you see here that they look at 17 sample 344 L and then six production samples, right? 18 A. Okay. 19 Q. And those are all different samples, 20 correct? 21 A. Yes. 22 Q. So they are six independent samples, 23 plus a seventh finished product sample, right? 24 A. Correct. 25 Q. And you could see, sir, that they</p>

<p style="text-align: right;">Page 26</p> <p>1 find tremolite/actinolite in six of the seven, 2 including the bottle of baby powder, 344 L, right? 3 A. Again, I'm not sure if 344 L is a 4 baby powder, but yes, they identify trace tremolite 5 actinolite by X-ray diffraction in that sample. 6 Q. And I asked you if that was a bottle 7 of baby powder, you said you believed it was? 8 A. I'm trusting you on that. I don't 9 know for sure without checking more documentation. 10 Q. Okay. Well, you told this jury about 11 the Langer story yesterday, right? 12 A. Um-hum. 13 Q. And the bottle that he was looking at 14 was 344 L, correct? 15 A. Okay. 16 Q. Okay. So here they report, and this 17 is on July 7, they report tremolite/actinolite in 18 six production samples and a bottle of baby powder, 19 right? 20 A. Five production samples and the 344 L 21 sample, yes. 22 Q. Correct. 23 One of the production samples was 24 non-detect, correct? 25 A. True.</p>	<p style="text-align: right;">Page 28</p> <p>1 right; June 30 and July 27, correct? 2 A. They do reference that. Yes. 3 Q. Now we go four days later. There's a 4 meeting at the FDA on August 3rd, 1971; correct, 5 sir? 6 A. I believe so. 7 Q. And this is Plaintiffs' Exhibit 2390. 8 I'll let you peek at this. Here is a copy if you 9 want. 10 A. Yeah. That's fine. 11 Q. Here's the last one, if you want to 12 look at it. 13 A. Thank you. 14 Q. All right. So August 3rd, 1971, 15 there's a meeting at the FDA. And if we want to 16 know who was there, at the end there's a attendance 17 list, correct? 18 A. Yes. On page 6. 19 Q. Johnson & Johnson brought one, two, 20 three, four, five, six, seven, eight, nine people, 21 correct? 22 A. Appears correct. 23 Q. Mr. Caneer is from the Colorado 24 School of Mines, right? 25 A. That's correct.</p>
<p style="text-align: right;">Page 27</p> <p>1 Q. The next exhibit is Plaintiffs' 2 Exhibit 2385. I'll let you look at it and then I'll 3 retrieve it. Okay? 4 A. Okay. 5 Q. Okay. You got it? 6 A. I do. 7 Q. So this is now July 29. So we just 8 looked at July 7. Now we're looking 22 days later. 9 And you can see this is an internal memo, right? 10 A. I see that. 11 Q. And you can see here it just says, 12 "The talc used in Johnson's Baby Powder is obtained 13 from a selected mine in Vermont where the ore 14 consists mainly of platy talc with only trace 15 amounts of fibrous minerals tremolite/asbestos 16 contaminated talc." 17 They call them fibrous minerals, 18 correct? 19 A. Correct. 20 Q. "It is free of chrysotile fibers 21 which may be called pure asbestos by the layman," 22 and they go on and they talk. 23 But down here you could see that they 24 have, they're discussing the Colorado School of 25 Mines' research reports that we have now looked at,</p>	<p style="text-align: right;">Page 29</p> <p>1 Q. And you could see that they -- 2 A. Which page are you on now? 3 Q. I'm just paging through it just to 4 give us a general appreciation. 5 Each person or many of the people 6 actually stood up and presented, correct? 7 A. That's typically what would happen at 8 a meeting like this, yes. 9 Q. All right. The next exhibit is 2391, 10 also 8/3rd. To get our bearings, what I'm showing 11 you now is Johnson & Johnson's minutes, their memo. 12 And now I'm going to show you the FDA's. Okay? 13 This is the FDA's copy. It's not quite as good. 14 But if you could see at the top 15 that's 8/3/71. And feel free to page through it, if 16 you'd like. 17 All right, sir. On the first page we 18 could see this is from August 3rd, '71, and this is 19 the FDA version. 20 Do you see that? 21 A. Yes, I do see that. 22 Q. And it says, "To specify a laboratory 23 purpose -- to specify a laboratory procedure for the 24 determination of asbestos in cosmetic talc powders 25 which will give consistent, meaningful results, this</p>

<p style="text-align: right;">Page 30</p> <p>1 may require answers to questions such as: Is there 2 a need to count not only asbestos fibers but also 3 non-asbestos fibers and fibrous talc," and it goes 4 on, correct? 5 A. Correct. 6 Q. I just want to go to the attendance 7 list on the next page. Starts here. Malcolm Ross, 8 and then you see the folks from Johnson & Johnson, 9 right? 10 A. Yes. 11 Q. And there's Mr. Caneer again, he's 12 from Colorado School of Mines; true? 13 A. Correct. 14 Q. And on the next page they have 15 presentations, Analytical Methods For Asbestos. And 16 there's Mr. Caneer again from Colorado School of 17 Mines, right? 18 A. Correct. 19 Q. If you turn to, again, this thing is 20 a rough copy, if you go to the page at the top it's 21 marked 5. So under the date -- 22 A. Yes. 23 Q. -- go halfway down, there's what 24 Mr. Caneer said. "W.T. Caneer, Colorado School of 25 Mines Research Institute. Reviewed petrographic and</p>	<p style="text-align: right;">Page 32</p> <p>1 finding chrysotile everywhere." Right? 2 A. You asked me if you read that 3 correctly? 4 Q. Yeah. 5 A. You read that correctly. 6 Q. That's what's in the reported 7 minutes, right? 8 A. Whoever wrote the minutes, that was 9 their interpretation. 10 Q. Right. 11 So we know there's this meeting on 12 8/3/71. So before that, we have the results of the 13 344 L, the baby powder, and the six production 14 samples where five are positive for tremolite 15 actinolite, correct? 16 A. For those minerals, yes. 17 Q. Then within a month or a month and a 18 half, there's a meeting at the FDA where Mr. Caneer 19 says the Johnson & Johnson samples represented clean 20 fiber, whatever that means, right? 21 A. I don't know what Mr. Caneer said. 22 That's what -- whoever wrote the minutes, that's 23 what they wrote. I don't know what Mr. Caneer would 24 have said at that time. 25 Q. That's fine.</p>
<p style="text-align: right;">Page 31</p> <p>1 electron probe studies of J&J." He's talking about 2 the Johnson & Johnson talc, right? 3 A. Correct. 4 Q. "Showed clean fiber"?</p> <p>5 A. That's what it says. 6 Q. Right? 7 Do you know what that means? 8 A. By that term, no, I'm not sure what 9 the author of this memo meant by that. 10 Q. Okay. Whatever he's saying, he's 11 saying the powder was clean somehow; fair? 12 A. Well, again, I don't know. Just 13 says, "showed clean fiber." You'd have to ask the 14 person who made the minutes to know what he meant at 15 that time. 16 Q. Okay. Then there was a mention here 17 about Mr. Geiger or Geiger. Geiger or Geiger was 18 with McCrone, correct? 19 A. I'm sorry, what page are you on. 20 Q. The very next page, page 6. 21 A. Yes. Mr. Geiger was at McCrone. 22 Q. And the author of this memo just 23 says, "Geiger questioned some of Art Langer's 24 identification of chrysotile fibrils. This was a 25 smokescreen, but a good counter-offensive to Langer</p>	<p style="text-align: right;">Page 33</p> <p>1 This is Exhibit 2381, Plaintiffs' 2 Exhibit 2381. This is three days later. And this 3 is a memo that you and Mr. Dubin went over 4 yesterday. This is three days after that meeting 5 with the FDA. And this is from the Colorado School 6 of Mines to Johnson & Johnson, right? 7 A. Correct. 8 Q. And it's from Maurice Pattengill, 9 M.G. Pattengill, right? 10 A. Yes. 11 Q. And it says, "After attending the 12 Washington meeting August 3rd, '71, and listening to 13 the arguments and data presented, I have the 14 following to add to the data previously sent to you 15 concerning the Vermont talc samples. In the report 16 of July 7, 1971, there is some question relative to 17 the presence of tremolite actinolite." 18 Remember, this is the one where they 19 found the tremolite actinolite in the baby powder 20 and the five of six production runs, correct? 21 A. That's correct, by X-ray diffraction, 22 yes. 23 Q. He says there's some question. "The 24 samples were prepared in a room that was not 25 entirely clean and were prepared in conjunction with</p>

<p style="text-align: right;">Page 34</p> <p>1 standard type asbestos samples. Subsequent X-ray 2 work on six monthly production samples and the 344 L 3 product sample shows no definite indications of any 4 asbestos type minerals within our limits of 5 detectability. The trace amounts I saw were 6 evidently contamination from standard asbestos 7 samples."</p> <p>8 So three days after the meeting with 9 the FDA, this guy from Colorado School of Mines 10 writes to Johnson & Johnson and said, you know, I've 11 been thinking about it, and I just realized that it 12 was actually contamination, right?</p> <p>13 A. That's what he reports. Yes.</p> <p>14 Q. Now, if you are aware that there's a 15 contamination issue in a lab, right, you immediately 16 rerun the samples, don't you; clean it up, you rerun 17 it?</p> <p>18 A. Once you become aware there may be an 19 issue, you would look into it. So depending when 20 your knowledge came that there may be an issue with 21 contamination is when you would take action.</p> <p>22 Q. And apparently this fellow's 23 knowledge came three days after a meeting with the 24 FDA, correct?</p> <p>25 A. That's what he states.</p>	<p style="text-align: right;">Page 36</p> <p>1 in attendance.</p> <p>2 Q. And there's the whole list. Do you 3 see his name on it?</p> <p>4 A. I can't do that. I'm going to go 5 crazy.</p> <p>6 Q. Here.</p> <p>7 A. That's fine. I have the document 8 here.</p> <p>9 You are correct, I do not see his 10 name.</p> <p>11 Q. So when we dig into the documents 12 what we see is that they had detected what they 13 detected. Then they had a meeting at the FDA. Then 14 a guy who wasn't there said after being there, I 15 remembered now that it was all contamination. 16 Pretty good summary?</p> <p>17 A. No, I don't think -- again, we do not 18 know what these lists represent. He says he was 19 there in the one letter. I have no idea how to 20 verify whether he's telling the truth or not.</p> <p>21 Q. Well, sir, we do know what the lists 22 represent; one is a prospective attendees list and 23 one is an attendees list, right?</p> <p>24 A. No. They talk about participants. 25 Being an attendee to a meeting and a participant in</p>
<p style="text-align: right;">Page 35</p> <p>1 Q. And he said, "After attending the 2 Washington meeting," right?</p> <p>3 A. Yes.</p> <p>4 Q. And it's signed by Maurice 5 Pattengill, right?</p> <p>6 A. That's correct.</p> <p>7 Q. Maurice Pattengill.</p> <p>8 Here's the meeting. Let's go to the 9 attendance list. Did Maurice Pattengill attend this 10 meeting according to the attendance list?</p> <p>11 A. Well, the list is a prospective 12 participants list. So again, we're talking about he 13 may not have participated. He may have been in 14 attendance, but he was not giving any information or 15 presenting any information.</p> <p>16 Q. Hold on, hold on. Look. Look at the 17 top. "The following people attended the symposium."</p> <p>18 A. Well, I'm looking at the FDA minutes 19 which talks about participant list.</p> <p>20 Q. So he's not on either. He's not on 21 the prospective participants list and he's not on 22 the attendance list, is he?</p> <p>23 A. I would have to check, but if you're 24 asking me the question, I assume he was not in 25 attendance, or at least he's not recorded as being</p>	<p style="text-align: right;">Page 37</p> <p>1 a meeting are different things.</p> <p>2 Q. Is his name on either of those?</p> <p>3 A. As I've stated, his name is not on 4 either of the documents.</p> <p>5 Q. That's the Colorado School of Mines.</p> <p>6 Let's talk a little bit about 7 Professor Lewin. This will be Exhibit 2852.</p> <p>8 Dr. Lewin was at NYU, right?</p> <p>9 A. That's my understanding. Yes.</p> <p>10 Q. And in August of 1972, in August of 11 1972, Dr. Lewin, who has been retained by the FDA, 12 reports a series of findings of asbestos in 13 different commercial talcs, correct?</p> <p>14 A. By X-ray diffraction, yes.</p> <p>15 Q. By XRD. Right. That's just to get 16 our bearings. That's August 3rd, 1972.</p> <p>17 He reports asbestos in two of 11 of 18 the Johnson & Johnson samples, correct?</p> <p>19 A. I believe that's accurate.</p> <p>20 Q. Now, XRD, at this time, had a 21 detection limit of about half a percent, correct?</p> <p>22 A. Actually with Dr. Lewin's work, I'm 23 not sure. I don't think he ever showed what his 24 detection limit was.</p> <p>25 Q. You wouldn't have expected it to be</p>

<p style="text-align: right;">Page 38</p> <p>1 less than that, correct?</p> <p>2 A. Not less than that, no.</p> <p>3 Q. Right.</p> <p>4 So even if we have something as low</p> <p>5 as half a percent detection limit by XRD, asbestos</p> <p>6 can be present in millions and billions of fibers</p> <p>7 per gram even at half a percent detection, correct?</p> <p>8 A. If it's there, it would just depend</p> <p>9 on how much is there.</p> <p>10 Q. Right.</p> <p>11 But you could have millions to</p> <p>12 billions of fibers per gram and not see it at all at</p> <p>13 half a percent detection limit?</p> <p>14 A. Well, by X-ray diffraction you can't</p> <p>15 even determine whether something is actually</p> <p>16 asbestos or not. But if you're talking about from a</p> <p>17 numerical count, yes, there would be many fibers of</p> <p>18 asbestos present in a sample which would have a</p> <p>19 concentration of, let's say, .1 percent.</p> <p>20 Q. XRD can detect chrysotile, can't it?</p> <p>21 A. No, it cannot. It only can -- it</p> <p>22 only is able to identify crystal structures, so it</p> <p>23 can detect whether you have serpentine minerals.</p> <p>24 There are other serpentine minerals other than</p> <p>25 chrysotile, so you have to still do further work.</p>	<p style="text-align: right;">Page 40</p> <p>1 because he is a member of the academic community and</p> <p>2 therefore, likely to be impartial in a confrontation</p> <p>3 between industry and Government.</p> <p>4 "Furthermore, his competence had</p> <p>5 previously been recognized by industry by virtue of</p> <p>6 their own use of him as a consultant which appeared</p> <p>7 to confer a desirable immunity against possible</p> <p>8 industry attacks on the validity of the results."</p> <p>9 Did I read that right?</p> <p>10 A. You did.</p> <p>11 Q. Of course, that didn't happen. His</p> <p>12 results were assailed by Johnson & Johnson and its</p> <p>13 consultants, correct?</p> <p>14 A. And others. But again, you look at,</p> <p>15 you look at what he was doing and whether it was</p> <p>16 feasible or not, what he was claiming, and it's not.</p> <p>17 Q. Okay. So let's look at some other</p> <p>18 documents and see what happened.</p> <p>19 So he did his first batch of testing</p> <p>20 by, I'll use a different marker, by XRD, right?</p> <p>21 A. He was using powder X-ray</p> <p>22 diffraction, yes.</p> <p>23 Q. This will be Exhibit 3441.</p> <p>24 Now, you're aware, sir, are you not,</p> <p>25 that Johnson & Johnson actually looked at some of</p>
<p style="text-align: right;">Page 39</p> <p>1 Q. Serpentine is the class into which</p> <p>2 chrysotile falls, correct?</p> <p>3 A. Mineral group, yes.</p> <p>4 Q. Then he issues a final report on</p> <p>5 7/31/73, and you and Mr. Dubin talked about his</p> <p>6 final results, right?</p> <p>7 A. I believe we showed some of them,</p> <p>8 yes.</p> <p>9 Q. I want to talk about what happened</p> <p>10 between those two dates, right, as we dig into the</p> <p>11 documents. But before that, so this is Exhibit</p> <p>12 1297.</p> <p>13 Professor Lewin was hired by the FDA</p> <p>14 to do this work because he was a renowned scientist,</p> <p>15 right?</p> <p>16 A. I'm sorry?</p> <p>17 Q. Dr. Lewin was hired by the FDA</p> <p>18 because he was a renowned scientist?</p> <p>19 A. Well, let's just read the language.</p> <p>20 They state, "The Internationally recognized expert</p> <p>21 on mineralogical chemistry."</p> <p>22 Q. Okay. All right. That's fine.</p> <p>23 The FDA says, "I chose Dr. Lewin for</p> <p>24 this work because he is an Internationally</p> <p>25 recognized expert on mineralogical chemistry and</p>	<p style="text-align: right;">Page 41</p> <p>1 Lewin's samples on its own internally?</p> <p>2 A. I am aware of that.</p> <p>3 Q. One of the folks who was at Johnson &</p> <p>4 Johnson was a fellow named Robert Rolle, and</p> <p>5 here's -- this is from his files; do you see that,</p> <p>6 from Robert Rolle or R. Rolle's files?</p> <p>7 A. I do.</p> <p>8 Q. Do you see, sir, that here's some</p> <p>9 notes about the Lewin samples of Shower to Shower,</p> <p>10 and he's dated it August 10, 1972. That's seven</p> <p>11 days after the FDA first got the report, correct?</p> <p>12 A. On that date, yes.</p> <p>13 Q. It says, "About one fiber or</p> <p>14 rod/needle every 500 particles." Correct?</p> <p>15 A. You read that correctly.</p> <p>16 Q. And that's in the Lewin sample of</p> <p>17 Shower to Shower, right?</p> <p>18 A. Yeah. I mean, the header says,</p> <p>19 "Lewin samples of Shower to Shower."</p> <p>20 Q. And you see it says, "Approximately</p> <p>21 one-third of these are tremolite"?</p> <p>22 A. Of the rods and needles that they're</p> <p>23 seeing for every 500 particles, yes.</p> <p>24 Q. Correct.</p> <p>25 And so on 8/10/72, J&J ID's, he says,</p>

<p style="text-align: right;">Page 42</p> <p>1 he uses three terms, fibers, rod, needle, tremolite, 2 correct?</p> <p>3 A. He says -- I'm sorry. Let's just 4 read it. "One fiber or rod needle every 500 5 particles."</p> <p>6 Q. Right.</p> <p>7 A. "One-third of these are tremolite. 8 Two-three rolled talc or talc shards."</p> <p>9 Q. So he identified fiber/rod/needle of 10 tremolite?</p> <p>11 A. Yes. In this context for quantities.</p> <p>12 Q. Now, for us to understand or to 13 characterize how much -- how many tremolite fibers 14 rods or needles that is, we kind of need to have an 15 understanding about what's in a bottle. So he says 16 they identify one every 500 particles.</p> <p>17 Now, 99.9 percent of what's in those 18 bottles is talc flakes, right?</p> <p>19 A. I've never done those calculations. 20 I don't know.</p> <p>21 Q. It's mainly talc?</p> <p>22 A. The majority of the mineral in a 23 cosmetic talc is talc, yes.</p> <p>24 Q. So as -- now, you're a mineralogist?</p> <p>25 A. I am.</p>	<p style="text-align: right;">Page 44</p> <p>1 completely guessing.</p> <p>2 Q. Let's just, for example, just do 3 something in the middle. Let's say it's ten 4 trillion. Okay?</p> <p>5 A. Okay.</p> <p>6 Q. Now, if you wanted to say, by in 7 terms of percentage of total particles, right, let's 8 say there was hypothetically, let's say there's 9 asbestos and the asbestos represents .00001. Okay?</p> <p>10 A. Percent by weight, not by particle.</p> <p>11 Q. Of the particles. We're going to say 12 it's of the particles because we can't do it by 13 weight, can we?</p> <p>14 A. You can do it all by weight. Yes. 15 You can do it either way.</p> <p>16 Q. Let's do it both ways then. I have 17 my calculator on my phone, so we can do that.</p> <p>18 So in terms of total particles, you 19 tell me, you said you haven't done the math. Let's 20 do the math. You tell me what math we have to do.</p> <p>21 A. So you want particle by particle 22 count?</p> <p>23 Q. Let's do particle first, then we do 24 weight.</p> <p>25 A. That's fine. You take your ten</p>
<p style="text-align: right;">Page 43</p> <p>1 Q. And a geologist?</p> <p>2 A. Kind of the same thing, but yes.</p> <p>3 Q. Okay. So if we have one, let's say, 4 22-ounce bottle, the number of total particles in 5 that bottle is astronomical, right?</p> <p>6 A. It would be a very large number of 7 particles, depending on the grind.</p> <p>8 Q. Let's say J&J, since that's what 9 we're here for.</p> <p>10 A. Um-hum.</p> <p>11 Q. That number easily would exceed 12 hundreds of trillions of particles, correct?</p> <p>13 A. I've never done the calculation, but 14 it would be a very large number.</p> <p>15 Q. I mean, we can agree it would exceed 16 hundreds of trillions of particles, can't we?</p> <p>17 A. Again, I would have to do the 18 calculations. These numbers get very big and are 19 hard to visualize. I'd have to make some assumption 20 and do a calculation.</p> <p>21 Q. Can we agree it would be trillions of 22 fibers -- I mean trillions of particles?</p> <p>23 A. It would be many, many particles. If 24 it's over trillions or hundreds of trillions or even 25 more, I wouldn't know as I sit here today. I'm</p>	<p style="text-align: right;">Page 45</p> <p>1 trillion --</p> <p>2 Q. So, let me see. Here, put it up 3 here.</p> <p>4 That's ten billion, right?</p> <p>5 A. Yes. There you go.</p> <p>6 Q. Is that ten trillion?</p> <p>7 A. That's ten trillion, yes.</p> <p>8 Q. Okay. Then what do I do?</p> <p>9 A. I believe you times that by .00 -- do 10 that, four zeros and a one, that gives you, then you 11 would have to convert from the percentage, you have 12 to also divide by another hundred.</p> <p>13 Q. Okay.</p> <p>14 A. If my math on the fly up here is 15 accurate.</p> <p>16 Q. That would be a million particles of 17 asbestos, right?</p> <p>18 A. Under your hypothetical, yes, and 19 present at that concentration.</p> <p>20 Q. Right.</p> <p>21 If there's only a trillion, right?</p> <p>22 A. Ten trillion.</p> <p>23 Q. If there's only ten trillion.</p> <p>24 Now, you said you wanted to do it by 25 weight. How do we do it by weight?</p>

<p style="text-align: right;">Page 46</p> <p>1 A. We would just -- well, we have a 2 22-ounce bottle, you have to take that percentage, 3 would be -- sorry. We have a 22-ounce bottle. 4 Q. Right. 5 A. And you are saying we have 0.0001 6 percent. So you divide 22 by that number again, and 7 I believe you'd still have to correct for the 8 percentage and divide by another hundred -- or, I'm 9 sorry, you'd times by a hundred, I apologize. Math 10 on the fly is always -- 11 Q. That's all right. 12 22 divided by .00001 equals, and now 13 what do I do? 14 A. I believe you times it by a hundred 15 to take it out of the percent. 16 Q. 220 million, correct? 17 A. Doesn't seem right. We've done 18 something wrong in the math. We can't have more 19 than the starting mass. 20 Q. You know what, instead of putting you 21 on the spot for math 'cause you are a 22 geologist/mineralogist, not a mathematician, neither 23 am I. 24 A. I can figure it out, just give me 25 time.</p>	<p style="text-align: right;">Page 48</p> <p>1 of tremolite every 1500 particles. Is that 2 accurate? 3 A. According to these numbers, yes. 4 Q. So he would be seeing something like 5 one out of every 1500. But if we have trillions and 6 trillions, that adds up, doesn't it? 7 A. Again, it would depend on how you 8 want to calculate the result, what those numbers 9 would be from a concentration standpoint. 10 Q. Going back to the Lewin story, this, 11 of course, is an internal document that Johnson & 12 Johnson had regarding his samples, correct? 13 A. Mr. Rolle, yes. 14 Q. The next document is Exhibit 2424. 15 This is going to be August 10, it's 16 dated August 10. It's a summary of an FDA meeting 17 from August 11, 1972. So we have talked about one 18 meeting about a year earlier. That was August 3rd, 19 1971. Now we're talking about almost exactly a year 20 later, right, if we're in August '72, correct? 21 A. Correct. 22 Q. So I'm going to go here to 8/11/72. 23 There's a meeting with FDA. 24 All right. Sir, do you see that this 25 is a summary of that FDA meeting that took place on</p>
<p style="text-align: right;">Page 47</p> <p>1 Q. That's fine. Let's do this, in terms 2 of sheer quantity, it's a lot of asbestos fibers 3 under this hypothetical, correct? 4 A. I mean, again, it's all in context. 5 You're talking about -- I think we need to time 6 that -- it's not one million 'cause that would also 7 be times by a hundred, so it would be 100 million. 8 Q. It would be 100 million particles? 9 A. I believe that's correct. The math 10 is wrong. 11 But again, you're looking -- so at 12 the end of that calculation, it's 100 million 13 particles out of ten trillion particles. 14 Q. That's right. 15 If there's ten trillion particles 16 there, at this concentration you would have 100 17 million particles? 18 A. That's correct. 19 Q. Okay. The reason I wanted to do that 20 is because he's saying about one fiber out of every 21 500 was a rod or needle and then a third of those 22 would be tremolite, right? 23 A. That's what he reports. 24 Q. Meaning, if we did the conversion on 25 that, he would be seeing about one fiber/rod/needle</p>	<p style="text-align: right;">Page 49</p> <p>1 8/11? 2 A. I do. 3 Q. And it says, "The CTFA, FDA and 4 Johnson & Johnson meeting can be summarized as 5 follows." And they give us some context. 6 "Johnson & Johnson provided hard data 7 showing that Shower to Shower is free of chrysotile 8 asbestos by electron microscopy, X-ray and light 9 microscopy on 15 batches, as well as on the actual 10 sample tested by Lewin. 11 "Lewin did not agree with McCrone's 12 interpretation of X-ray data; however, he could not 13 satisfactorily explain the absence of chrysotile 14 asbestos fibers in the electron microscopy grids. 15 He said it may be asbestos growing inside the 16 platelets of talc. 17 "On the basis of our data, CTFA was 18 able to say that the Lewin report is incomplete 19 since it relied only on an X-ray assay which must be 20 confirmed by microscopy." Right? 21 A. You read that correctly. 22 Q. So they are saying look, it's got to 23 go confirmed by, and this would be light microscope, 24 correct, optical? 25 A. They don't specify. The earlier</p>

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<p>1 paragraph speaks of electron microscopy of the Lewin 2 samples.</p> <p>3 Q. We can turn the page and see what it 4 says. Paragraph 7, "Dr. Schaffner" -- who we know 5 is FDA, we've heard his name before -- "asked 6 Dr. Lewin to tell the group what work he proposed to 7 do to confirm his X-ray findings. After some 8 discussion, Dr. Lewin said that to be able to say 9 that a sample contained asbestos, the X-ray results 10 have to be confirmed by light microscopy."</p> <p>11 All right? Do you see that?</p> <p>12 A. That's what Lewin proposed to do, 13 yes.</p> <p>14 Q. That's right.</p> <p>15 "If no asbestos tremolite or 16 chrysotile is seen, the sample is declared to be 17 free of asbestos.</p> <p>18 "In subsequent discussions, Mr. Ian 19 Stewart pointed out that light microscopy may not 20 detect chrysotile fibers. Dr. Weissler said they 21 recognize that some samples will be passed on that 22 basis, but they are willing to live with that."</p> <p>23 First of all, did I read that right?</p> <p>24 A. You did.</p> <p>25 Q. So what they're doing now is the</p>	<p>1 A. Are you reading something now?</p> <p>2 Q. I'm asking -- you've been supplied 3 many, many hundreds of Johnson & Johnson documents, 4 correct?</p> <p>5 A. I have. Yes.</p> <p>6 Q. And I presume you've gone through 7 them all?</p> <p>8 A. I have, the ones that have been given 9 to me.</p> <p>10 Q. Okay. Let's just read it together 11 then.</p> <p>12 "Dr. Schaffner said that this 13 procedure will be adopted in the proposed policy 14 statement. He asked if anyone present had any 15 toxicological objections to the allowance of one 16 percent weight for weight asbestos in talc. One 17 percent is the limit of detection by X-ray, i.e., a 18 non-detectable asbestos X-ray result may mean up to 19 one percent asbestos being present. No objections 20 were raised."</p> <p>21 Did I read that right, first of all?</p> <p>22 A. That's correct.</p> <p>23 Q. So what they were proceeding with was 24 to verify Lewin with a method that, one, would not 25 see all the chrysotile fibers, correct?</p>
Page 51	Page 53
<p>1 proposal is that he confirm his results, he did it 2 with XRD, this non-microscope, and then confirm it 3 with optical microscopy, right?</p> <p>4 A. I don't agree with how you 5 characterized that. Dr. Schaffner asked Dr. Lewin 6 to tell the group what he had proposed to confirm. 7 Dr. Lewin said he would confirm it with light 8 microscopy.</p> <p>9 Q. Okay. That's fine. I agree with 10 you.</p> <p>11 So Lewin says he'll confirm -- "Lewin 12 to confirm with optical, but a problem is identified 13 with" --</p> <p>14 A. Dr. Ian Stewart of McCrone.</p> <p>15 Q. By McCrone, right?</p> <p>16 A. Correct.</p> <p>17 Q. And McCrone says it may not detect 18 the chrysotile fibers, right?</p> <p>19 A. That's correct.</p> <p>20 Q. Okay. Now, many, in fact, the 21 majority of Lewin's findings were chrysotile, 22 correct?</p> <p>23 A. By X-ray diffraction, yes.</p> <p>24 Q. This approach was approved by the 25 whole group, wasn't it?</p>	<p>1 A. May not see it, yes.</p> <p>2 Q. Okay. And no one objected to a one 3 percent allowance of asbestos, including Johnson & 4 Johnson, correct?</p> <p>5 A. Again, this was -- I think you're 6 mischaracterizing what is happening here.</p> <p>7 May I explain?</p> <p>8 Q. Let's see if we could clarify it.</p> <p>9 "He asked if anyone present" -- 10 Johnson & Johnson was present, correct?</p> <p>11 A. The FDA asked if anybody was present. 12 This is what they proposed to do to resolve the 13 Lewin issue that was presently facing the committee.</p> <p>14 Q. I appreciate that.</p> <p>15 "He asked if anyone present" -- 16 Johnson & Johnson was present, correct?</p> <p>17 A. Um-hum.</p> <p>18 Q. Yes?</p> <p>19 A. Yes. Sorry.</p> <p>20 Q. Sorry.</p> <p>21 A. Non-verbal, I apologize.</p> <p>22 Q. For Andrea, I'm sorry.</p> <p>23 "If anyone present had any 24 toxicological objections to the allowance of one 25 percent by weight asbestos in talc." Right?</p>

<p style="text-align: right;">Page 54</p> <p>1 A. That was the question.</p> <p>2 Q. "And that a non-detectable XRD or</p> <p>3 X-ray result may mean up to one percent asbestos is</p> <p>4 actually present." Correct?</p> <p>5 A. That's correct.</p> <p>6 Q. Nobody objected, including Johnson &</p> <p>7 Johnson, correct?</p> <p>8 A. That is -- nobody objected, yes.</p> <p>9 Q. And it says that "Dr. Lewin promised</p> <p>10 to complete his confirmatory phase 43 samples by</p> <p>11 October 1st." Right?</p> <p>12 A. That's what it states.</p> <p>13 Q. Now, the optical that Ian Stewart,</p> <p>14 who at the time was Johnson & Johnson's consultant,</p> <p>15 right?</p> <p>16 A. That's correct.</p> <p>17 Q. He said optical won't find the</p> <p>18 chrysotile, correct?</p> <p>19 A. May not find the finest fibers of</p> <p>20 chrysotile, yes.</p> <p>21 Q. And so when he issued his final</p> <p>22 report, the optical did not confirm the chrysotile,</p> <p>23 did it?</p> <p>24 A. That is, nobody found any chrysotile</p> <p>25 in the samples by optical microscopy, true.</p>	<p style="text-align: right;">Page 56</p> <p>1 Q. Which is, at least according to that</p> <p>2 meeting minutes from August 11, '72, that was good</p> <p>3 to about one percent, right?</p> <p>4 A. Well, what Lewin was doing he said</p> <p>5 was down to one percent. Buerger may have had a</p> <p>6 lower detection limit.</p> <p>7 Q. May have. Do you know what it was?</p> <p>8 A. I'd have to review his report if it's</p> <p>9 in there or not.</p> <p>10 Q. In all fairness, just us talking</p> <p>11 here, it's probably between half a percent and one</p> <p>12 percent; is it not, sir?</p> <p>13 A. It can get down to .1 depending on</p> <p>14 the instrumentation and how it's run. But the</p> <p>15 lowest you could probably get it with what they were</p> <p>16 doing back then was .01.</p> <p>17 Q. Do you know what --</p> <p>18 A. 0.1, I apologize.</p> <p>19 Q. Do you know what his sensitivity was?</p> <p>20 A. I'm not sure. I'd have to --</p> <p>21 Q. Whether it was --</p> <p>22 A. -- whether he reported or not.</p> <p>23 Q. -- one or .1?</p> <p>24 A. Again, I'd have to review. That's</p> <p>25 all I'm saying.</p>
<p style="text-align: right;">Page 55</p> <p>1 Q. He confirmed a result using a method</p> <p>2 that they knew might not see the chrysotile,</p> <p>3 correct?</p> <p>4 A. No. That's incorrect. There's</p> <p>5 issues of sometimes when you have very small</p> <p>6 chrysotile fibers, PLM will not be able to resolve</p> <p>7 them. That is the concern raised by Ian Stewart of</p> <p>8 Walter McCrone.</p> <p>9 Q. Right.</p> <p>10 Ian Stewart said it might not see all</p> <p>11 the chrysotile present, correct?</p> <p>12 A. Correct.</p> <p>13 Q. That method is what Lewin used to,</p> <p>14 quote, unquote, confirm his previous findings,</p> <p>15 correct?</p> <p>16 A. That is what Lewin proposed to do,</p> <p>17 and the FDA agreed to it and told him to do it.</p> <p>18 Q. Now, another document -- let's see</p> <p>19 here. Before I move on from Lewin, which I'm about</p> <p>20 to do, some of the documents you went through</p> <p>21 yesterday talked about some of Johnson & Johnson's</p> <p>22 consultants. There was Buerger, is it B-e-u --</p> <p>23 A. B-u-e-r-g-e-r.</p> <p>24 Q. Buerger, M.I.T. He did XRD, right?</p> <p>25 A. That's correct.</p>	<p style="text-align: right;">Page 57</p> <p>1 Q. I'm going to put a question mark.</p> <p>2 The next guy was Brown at Princeton,</p> <p>3 and he did XRD as well, right?</p> <p>4 A. That's correct.</p> <p>5 Q. Then there was Colorado School of</p> <p>6 Mines, and they did XRD, correct?</p> <p>7 A. In part, yes.</p> <p>8 Q. Then there was Carnegie, and they did</p> <p>9 XRD, right?</p> <p>10 A. That's correct.</p> <p>11 Q. And then there was Pooley. He did a</p> <p>12 few things, including electron microscopy, right?</p> <p>13 A. Correct.</p> <p>14 Q. And then there was McCrone, who did a</p> <p>15 few things, including TEM, right?</p> <p>16 A. Correct.</p> <p>17 Q. Now, we did this hypothetical, you</p> <p>18 and I, where we said, and this is just assuming,</p> <p>19 just assuming there's only ten trillion in a bottle</p> <p>20 and it's present at .00 -- 00001, right, XRD, it</p> <p>21 would be negative, negative, negative, negative.</p> <p>22 Correct?</p> <p>23 A. If that was the actual situation.</p> <p>24 Q. Okay. XRD is still the first step of</p> <p>25 Johnson & Johnson's biweekly testing for its talc,</p>

<p style="text-align: right;">Page 58</p> <p>1 isn't it?</p> <p>2 A. No, it is not.</p> <p>3 Q. Johnson & Johnson uses J4-1, correct?</p> <p>4 A. Not for the testing we do for them.</p> <p>5 We follow the current U.S.P., but we do mandatory</p> <p>6 microscopy. We don't rely upon the results of</p> <p>7 powder X-ray diffraction.</p> <p>8 Q. Right.</p> <p>9 We're talking about their actual</p> <p>10 testing frequency. Okay?</p> <p>11 A. Yes.</p> <p>12 MR. PANATIER: I'm sorry?</p> <p>13 MR. DUBIN: We're having trouble</p> <p>14 hearing.</p> <p>15 A. Okay.</p> <p>16 THE COURT: Even with the microphone,</p> <p>17 you do have to speak up.</p> <p>18 A. I'll bring it closer. Hopefully that</p> <p>19 helps.</p> <p>20 MR. MAIMON: If he wants to put it on</p> <p>21 the ledge, it would be higher.</p> <p>22 THE COURT: Try the ledge. Let's see</p> <p>23 how that works.</p> <p>24 Thank you.</p> <p>25 BY MR. PANATIER:</p>	<p style="text-align: right;">Page 60</p> <p>1 A. I think the requirement is you have</p> <p>2 to at least get to .5 to be able to run the method</p> <p>3 as stated, yes.</p> <p>4 Q. So if XRD doesn't pick up the</p> <p>5 presence of one of the minerals that can constitute</p> <p>6 asbestos, under that method you stop and you sell</p> <p>7 the talc, correct?</p> <p>8 A. If you follow that method explicitly,</p> <p>9 yes.</p> <p>10 Q. Only if you pick it up at greater</p> <p>11 than half a percent or thereabouts do you go and do</p> <p>12 optical microscopy, correct?</p> <p>13 A. That's correct.</p> <p>14 Q. And the method is only for amphibole,</p> <p>15 correct?</p> <p>16 A. As written, yes.</p> <p>17 Q. Not chrysotile, correct?</p> <p>18 A. That is correct.</p> <p>19 Q. Let's chat about this document that</p> <p>20 you discussed yesterday with Mr. Dubin. Here you</p> <p>21 go, sir. And this is exhibit -- I don't know what</p> <p>22 exhibit this is. Here you go. But it's in</p> <p>23 evidence.</p> <p>24 It's dated August 6, 1971. And</p> <p>25 interestingly, that's the same day that</p>
<p style="text-align: right;">Page 59</p> <p>1 Q. So now you actually, you have a large</p> <p>2 number of children, don't you?</p> <p>3 A. I have children, yes.</p> <p>4 Q. Just speak like you're trying to get</p> <p>5 them to dinner. Okay? All right.</p> <p>6 Now, let's talk about J4-1. Okay?</p> <p>7 J4-1 was the industry test adopted in about 1977,</p> <p>8 correct, or '76?</p> <p>9 A. In conjunction with the FDA, but yes,</p> <p>10 it was the industry standard at that time.</p> <p>11 Q. Okay. And the way that worked, quite</p> <p>12 simply, is an XRD test is done, right?</p> <p>13 A. I described this in my direct. Yes.</p> <p>14 Q. Okay. If XRD finds nothing, nothing</p> <p>15 further is done, right?</p> <p>16 A. If you are following the method</p> <p>17 exactly, yes.</p> <p>18 Q. If it finds something, then you do</p> <p>19 optical or light microscope, correct?</p> <p>20 A. That is correct.</p> <p>21 Q. Okay. There is no TEM in J4-1,</p> <p>22 correct?</p> <p>23 A. That is correct.</p> <p>24 Q. Okay. And so they actually describe</p> <p>25 a .5 detection limit, correct?</p>	<p style="text-align: right;">Page 61</p> <p>1 Mr. Pattengill wrote to Johnson & Johnson saying</p> <p>2 that he remembered that all those results were</p> <p>3 contamination.</p> <p>4 Do you recall that?</p> <p>5 A. That's not what he said. He reported</p> <p>6 that based upon him attending the FDA meeting, he</p> <p>7 had reason to question what he had -- what had been</p> <p>8 reported. And then he went back, it appears, and</p> <p>9 tried to -- investigated that and reported to</p> <p>10 Johnson & Johnson.</p> <p>11 Q. Three days after the meeting, he said</p> <p>12 he remembered it, right?</p> <p>13 A. No. He says from attending the</p> <p>14 meeting, something happened at the meeting that made</p> <p>15 him think of that as a possibility, I am assuming.</p> <p>16 But he attended the meeting, obtained some</p> <p>17 information, went back to check some of his reports</p> <p>18 and thought there was an issue and reported it.</p> <p>19 Q. Is it reasonable to think that what</p> <p>20 made him think about this, maybe it was</p> <p>21 contamination all of a sudden, is that Mr. Canear</p> <p>22 was reporting clean fibers to the FDA?</p> <p>23 A. I can't draw those -- I have no idea</p> <p>24 what was said at that meeting and what was meant by</p> <p>25 clean fiber in the FDA meeting minutes.</p>

1 Q. You talked about this document from 2 August 6, '71. 3 A. Yes. 4 Q. Where Mr. Ashton says, "I have 5 checked into the mineralization of that part of the 6 territory"? 7 A. Correct. 8 Q. You recall that? 9 A. I do. 10 Q. And he said that the minerals 11 included, you know, a number of things, but there's 12 chrysotile, tremolite and actinolite, right? 13 A. Yes. 14 Q. Okay. And he's talking about 15 shipping a drum from the Crosetto mine in the 16 Chisone Valley of the Italian Alps, right? 17 A. That's what it states. 18 Q. Now, the Johnson & Johnson mine that 19 they actually got their talc from is called the 20 Fontaine or the Fontana mine, correct? 21 A. It can be called that. Yes. 22 Q. Okay. And, sir, did you say 23 something about does this have anything to do with 24 Fontana yesterday? 25 A. Mr. Dubin said that.	Page 62 1 Q. Let's talk about Dr. Langer. And I 2 only have a couple documents for Dr. Langer. This 3 one will be Exhibit 2374. 4 So Dr. Langer, the story you told 5 about Dr. Langer was that Dr. Langer had said he 6 found asbestos and then unsaid he found asbestos 7 basically, right? 8 A. No. I think his article said he may 9 have been mistaken. He actually didn't do the 10 analytical work necessary to conclude that he had 11 found asbestos. 12 Q. Okay. Tell me if this sounds right 13 as to what the story was. 14 Initially they had a preliminary 15 report that said five to 25 percent asbestos. He 16 said that was incorrect, that was preliminary. 17 Correct? 18 A. The numbers escape me exact, but I'll 19 take your representation. 20 Q. All right. That doesn't sound like 21 it's incorrect, does it? 22 A. No, it doesn't. 23 Q. He always maintained there was trace 24 asbestos. And, by the way, when we talk about these 25 numbers of .00001, that's scientifically, you call
Page 63 1 Q. Yeah. I think you agreed with him, 2 didn't you? 3 A. No. I've reviewed my testimony, but 4 where Crosetto is and Fontana, they're across the 5 valley. Those are both located at Val Germanasca. 6 I made the distinction, I believe, 7 when I answered Mr. Dubin's question, that Val 8 Chisone is a different valley where the mills are 9 located. The actual mines are all up in Val 10 Chisone. Both Crosetto area and in the Fontana 11 area. 12 Q. Right. 13 So this would be the talc that they 14 are talking about putting into their baby powder, 15 correct? 16 A. Possibly, assuming they were getting 17 it from the Crosetto side. The records appear to be 18 they were getting it from the other side of the 19 valley, but it potentially could be. 20 Q. It's the same overall geological 21 deposit, isn't it? 22 A. Yes. You literally have this, you 23 have like a fold of a talc body in there and then 24 the mountains have gone up and then erosion has cut 25 out the center part.	Page 65 1 that trace or sub trace, correct? 2 A. It really depends. Usually you 3 report out something as trace that's below your 4 detection limit. So depending on the methodology 5 you are using would define what you're meaning by 6 trace. 7 Q. Okay. So it differs from scientist 8 to scientist? 9 A. No. It would differ between the 10 testing being done. For example, if you were 11 performing X-ray diffraction and there was an 12 amphibole in there that was below your limit of 13 detection, you could report it out as trace. Or you 14 lower your ability to quantify it, you would be 15 trace. 16 If you're doing TEM, a concentration 17 below your ability to quantify it would be a trace 18 amount. You wouldn't be able to give any number to 19 it. So you just report it as trace, meaning it's 20 less than your detection limit with the methodology. 21 Q. Meaning you identify it there, but 22 based on your methodology you can't quantify it. 23 Correct? 24 A. That is one way to use trace, yes. 25 Q. So this is from, you should have

<p style="text-align: right;">Page 66</p> <p>1 this, this is a Johnson & Johnson note, and it's a 2 report of a call from June 19, and I'll represent 3 this is 1972. Okay?</p> <p>4 "Dr. Langer, Mount Sinai School of 5 Medicine, called just before lunch. He has a favor 6 to ask. Would Dr. Nashed please have sent to him a 7 sample of sodium sesquicarbonate. He has been trying 8 to get a sample for some time and has not been 9 successful."</p> <p>10 That is not important. Here's what's 11 important. Down here. Right here.</p> <p>12 2:30 p.m., "Dr. Nashed called. I 13 gave message and he questioned: Would it be to our 14 interest to have a comparison of sodium 15 sesquicarbonate and chrysotile? Would it get 16 Dr. Langer away from insisting that he believes we 17 may have trace amounts of asbestos in our talc? He 18 said, Call Dr. Rolle."</p> <p>19 See that?</p> <p>20 A. I do.</p> <p>21 Q. "Called Dr. Rolle. He said he didn't 22 see any harm in sending it to Langer, but he feels 23 that Langer is not going to retract his statement 24 and as a scientist, will stick by his feeling that 25 there may be traces of asbestos in our talc."</p>	<p style="text-align: right;">Page 68</p> <p>1 A. They met with him on numerous 2 occasions, but yes.</p> <p>3 Q. If you turn to the third page, "light 4 and electron microscopy of Johnson's Baby Powder."</p> <p>5 Do you see that?</p> <p>6 A. I do.</p> <p>7 Q. "Langer demonstrated his technique 8 for observing fibrous minerals in Johnson's Baby 9 Powder." And it talks about his process.</p> <p>10 "After examining the sample in the 11 light microscope for a short time, he stated that he 12 could pick up some non-plate particles that could be 13 amphiboles or other asbestos forms or fibrous talc 14 or in my opinion," that's the Johnson & Johnson 15 writer, "talc fragments."</p> <p>16 Now, that's light microscope, right?</p> <p>17 A. That's correct.</p> <p>18 Q. He said, "He estimates the amount in 19 the sample to be on the order of one or two 20 percent."</p> <p>21 Let's go down to electron. "Using 22 electron microscopy, Dr. Langer has demonstrated to 23 me the presence of some very fine fibers at 24 moderately high magnification which he identifies as 25 chrysotile asbestos." Correct?</p>
<p style="text-align: right;">Page 67</p> <p>1 Right?</p> <p>2 A. You read that correctly.</p> <p>3 Q. At least as of June 1972, he's saying 4 there's traces of asbestos in talc, correct?</p> <p>5 A. That's not what he's saying. This is 6 what Dr. Rolle thinks is that he will say.</p> <p>7 Q. The Johnson & Johnson person reported 8 this in this memo, correct?</p> <p>9 A. Yes. He says he feels, meaning 10 Dr. Rolle feels, that Dr. Langer is not going to 11 retract his statement.</p> <p>12 Q. Okay. Well, that's fine. I think we 13 have some information directly from Dr. Langer. So 14 that was 6/19/71. The next exhibit is 2382. I'll 15 just show you this one.</p> <p>16 A. Thank you.</p> <p>17 Q. Okay. Sir, do you see that this is a 18 memo of a meeting with Dr. Langer about three weeks 19 later on July 9?</p> <p>20 A. That's correct.</p> <p>21 Q. It says, "Meeting with Dr. Langer on 22 July 9 concerning analytical analysis of talc."</p> <p>23 Right?</p> <p>24 A. Correct.</p> <p>25 Q. They actually met with the guy; true?</p>	<p style="text-align: right;">Page 69</p> <p>1 A. You read that correctly.</p> <p>2 Q. So this is three weeks later he shows 3 them what he was talking about in the previous phone 4 call, correct?</p> <p>5 A. He shows what he believes is the 6 chrysotile that he's seeing, yes.</p> <p>7 Q. All right. He's at Mount Sinai, 8 right?</p> <p>9 A. That's correct.</p> <p>10 Q. This next one is Plaintiffs' 2403. 11 He actually writes them a letter, doesn't he, later 12 that year? Actually, this was the year before.</p> <p>13 A. This is from 1971. Yes.</p> <p>14 Q. November 10, '71, he actually wrote 15 them a letter; true?</p> <p>16 A. Correct.</p> <p>17 Q. You see this is from Mount Sinai?</p> <p>18 A. I do.</p> <p>19 Q. To Gavin Hildick-Smith?</p> <p>20 A. Yes.</p> <p>21 Q. At J&J, right?</p> <p>22 A. Correct.</p> <p>23 Q. He says that "Electron 24 diffraction" -- meaning he's doing electron 25 microscopy, correct?</p>

1 A. Yes. 2 Q. "Electron diffraction on these grains 3 again yield the grains -- again yields a talc 4 pattern which is very definitely defined -- 5 well-defined hexagonal array of spots. We also 6 observed trace amounts of chrysotile asbestos only 7 when the talc was sonified and markedly dispersed." 8 Sonified just means that, as far as 9 my understanding is, you put it in a solution and 10 then you use a sonicator, which is a very, very 11 rapidly vibrating pad, and you stick it on there and 12 it goes "bzzz," and it disperses everything inside 13 that tube, correct? 14 A. That's one type of sonication device. 15 Q. So anyway, he writes them and says 16 they identify chrysotile asbestos, correct? 17 A. After the sonication, yes. 18 Q. It says, "The amounts are relatively 19 small occurring in amounts we estimate at less than 20 .01 percent." He says, "The J&J baby talc is of 21 quite high quality and as a matter of fact, in 22 relation to the number of samples we have examined 23 thus far, it is the purest." Right? 24 A. That's what he states. 25 Q. Still contains asbestos, right?	Page 70	1 Q. And he said I don't see any issue 2 in -- 3 A. Sending him the sodium sesquihydrate 4 so he could look at that, yes. 5 Q. Then three weeks later they're in 6 Langer's lab and they're looking at it and he says 7 here's the chrysotile? 8 A. They're looking at it, but again, if 9 you read the memo, they're not doing the diffraction 10 work. It's simply again looking at the morphology 11 of the particles. 12 Which is important about the sodium 13 sesquihydrate because again, it has an appearance 14 similar to chrysotile. So if you're only looking at 15 the appearance of the particles, that is an 16 interference. 17 Q. You didn't ever look at any of these 18 particles, this is just your speculation as to what 19 could have happened, correct? 20 A. It is my interpretation of looking at 21 the documents and the records. The sodium 22 sesquihydrate was known to be an interference of 23 chrysotile in creating very thin, tubular-like 24 fibers. So there was concern when you're not doing 25 the diffraction, which Langer was not doing in the	Page 72
1 A. That's what he's reporting here, yes. 2 Q. So this is the third communication 3 from Dr. Langer that you and I have discussed where 4 he reaffirms the presence of asbestos; true? 5 A. I don't think it's reaffirming 6 anything. We're talking about an original report 7 here versus subsequent work that was being done. 8 Q. Well, one time he writes a letter 9 where he said he did work, found it, right? 10 A. In '71, yes. 11 Q. Then in '72 they call him and he 12 reiterates it's there, correct? 13 A. No. No. Dr. Rolle, they were 14 calling Dr. Rolle to see if it was worth sending him 15 the sodium sesquihydrate. Sodium sesquihydrate has 16 a very similar appearance to chrysotile. That was 17 an issue back then. 18 And so the discussion was whether 19 sending the sodium sesquihydrate to Langer would be 20 good for him to be able to look at that material and 21 see if it was the same as the material he was seeing 22 in the powders that he was calling chrysotile. 23 Dr. Rolle said that he wouldn't, he 24 didn't know what would happen, he would thought that 25 Dr. Langer would stand by what he said.	Page 71	1 '72, he was simply looking for tubular fibers. 2 So again, if you're not doing your 3 analytical work to the rigor necessary, you cannot 4 conclude that you have something. Langer's results 5 are incomplete. They're not scientifically 6 reliable. 7 Q. Sir, you never looked at a single one 8 of his samples, have you? 9 A. That has nothing to do with it, sir. 10 I am looking at the record. We are talking about 11 the record of what he was doing to make these 12 findings. His analytical procedures, what he says 13 he was doing is incapable of drawing those 14 conclusions scientifically. 15 Q. We'll see what he says because he's 16 talked about this, okay, which we'll get to. 17 This is from June 17, 1972. And this 18 is a memo to file by, I believe it's, yeah, Nashed. 19 THE COURT: What's the marking on 20 that, please? 21 MR. PANATIER: This one is 2364, your 22 Honor. 23 THE COURT: Thank you. 24 BY MR. PANATIER: 25 Q. Here's a copy.	Page 73

<p style="text-align: right;">Page 74</p> <p>1 Top of page 2. "I asked Langer if he 2 can state that our baby powder is free of asbestos 3 as a result of the conference and review of August 4 3rd, 1971, with the FDA. He said he still thinks 5 Johnson & Johnson's product contains minute traces 6 of asbestos and he believes he can find asbestos 7 fibers after breaking down the platelets with 8 ultrasonic energy." Correct?</p> <p>9 A. That's correct.</p> <p>10 Q. That's June '72.</p> <p>11 Sir, you know that as recently as 12 last year he reaffirmed what he did at Mount Sinai, 13 correct?</p> <p>14 A. I don't know that.</p> <p>15 MR. DUBIN: I object.</p> <p>16 MR. PANATIER: It's in evidence.</p> <p>17 THE COURT: Sidebar. (Sidebar.)</p> <p>18 MR. DUBIN: Just for the record --</p> <p>19 THE COURT: Well, now I'm here.</p> <p>20 MR. DUBIN: We're now talking about 21 whatever Dr. Langer said in the New York Times 22 article that post-dates historical documents that 23 we've been discussing during a time period when, for 24 example, Dr. Sanchez has done all the testing work,</p>	<p style="text-align: right;">Page 76</p> <p>1 MR. PANATIER: Yeah. 2 (Sidebar ends.)</p> <p>3 BY MR. PANATIER:</p> <p>4 Q. All right. So this is the last 5 Langer thing we're going to look at. I'll just let 6 you see it.</p> <p>7 You see this is an article from The 8 New York Times from December 14, 2018?</p> <p>9 A. Okay.</p> <p>10 Q. Go ahead and turn to the next page.</p> <p>11 Just take a look at that excerpt and then I'll ask 12 you some questions about it.</p> <p>13 MS. BROWN: Counsel, we have a copy.</p> <p>14 MR. PANATIER: That's fine. Hold 15 onto that one then, Dr. Sanchez.</p> <p>16 BY MR. PANATIER:</p> <p>17 Q. Now, assume nothing from the 18 blackout. Sometimes courts, we have to do this for 19 different reasons. Okay?</p> <p>20 But you see this is from The New York 21 Times, we don't know the title, but from 22 December 14, 2018?</p> <p>23 Do you see that?</p> <p>24 A. I do.</p> <p>25 Q. Okay. And there's a quote from</p>
<p style="text-align: right;">Page 75</p> <p>1 advised the company about what he has and has not 2 found back in the 1970s. I'm not permitted to get 3 into a long with the fact that I'm not allowed to 4 get into real changes and things that their experts 5 have said. And I think this is far afield from what 6 I was allowed to ask Dr. Sanchez about, which was 7 the historical record of these documents. So I 8 would object with this witness.</p> <p>9 MR. PANATIER: He asked him, they 10 went completely over Langer, and they said that we 11 had misrepresented Langer's findings on the boards. 12 And he said we have to dig into the documents. 13 That's what I'm doing.</p> <p>14 THE COURT: I'll allow it.</p> <p>15 Before we leave, Ercilyn notified me 16 that she can hear your conversations. I -- the 17 official record cannot have that. So if you need to 18 get closer --</p> <p>19 MR. DUBIN: Okay. I'm just trying to 20 gather all the documents.</p> <p>21 THE COURT: I know. The voices that 22 I'm concerned about, I don't want your discussions 23 to be on the record.</p> <p>24 MR. DUBIN: Okay. No problem.</p> <p>25 THE COURT: Take a break at 10:30.</p>	<p style="text-align: right;">Page 77</p> <p>1 Dr. Langer. "In a recent interview, Dr. Langer -- 2 Mr. Langer told the times that Dr. Chalmers spoke 3 for himself and for the institution, not our 4 research group. He reiterated that his team had 5 detected asbestos in Johnson's Baby Powder. I stand 6 by that today, absolutely," he said.</p> <p>7 Now, did I read that right?</p> <p>8 A. You did.</p> <p>9 Q. Is that the first time you've seen 10 that?</p> <p>11 A. I don't know if I've seen this or not 12 before with all the redactions. I'm sorry.</p> <p>13 Q. Sir, you're aware -- you talked about 14 the FDA. You're aware, in approximately '73 or '74, 15 the FDA found approximately 107,000 fibers per gram 16 of tremolite in Johnson's Shower to Shower, correct?</p> <p>17 A. I've seen an internal document from 18 the FDA using an optical technique reporting that, 19 yes.</p> <p>20 Q. When you were talking about 21 Dr. Pooley -- maybe I'll come back to that. I don't 22 know it's that important.</p> <p>23 Okay. We will do this one. This 24 will be Exhibit 2049. It's Argonaut.</p> <p>25 Johnson & Johnson was aware, sir,</p>

<p style="text-align: right;">Page 78</p> <p>1 that both its Hammondsville ore body and its 2 Argonaut ore body contained levels of chrysotile 3 asbestos by virtue of their own core sampling, 4 correct? 5 A. In certain areas, yes. 6 Q. This is Exhibit 2049. The jury has 7 seen this. "Examination of talc samples from the 8 ore body." And all I want to do is look at some of 9 these percentages. 10 First of all, they took core samples, 11 38 core samples, right? 12 A. Correct. This is discussing the 13 Argonaut ore body, yes. 14 Q. Right. 15 But they also compared it to three 16 then current which are listed here at the very 17 bottom of Table 1. 18 A. Current. 19 Q. Have you reviewed this before, sir? 20 A. I have. Yes. 21 Q. Okay. If you go under the summary on 22 the first printed page -- 23 A. I'm there. 24 Q. -- do you see at the end of the first 25 comparison they say, "For comparison, three core</p>	<p style="text-align: right;">Page 80</p> <p>1 A. Correct. 2 Q. Okay. So when we go back to our 3 math, what they said was they had one that exceeded 4 .0005 percent, which in a matter of percentage is 5 greater than .00001 percent, correct? 6 A. Correct. 7 Q. And they had 15 where they found 8 chrysotile asbestos, right, in the 38 core samples 9 for Argonaut; true? 10 A. Is that what they said? Hold on. 11 Give me a second to check that. 12 Correct. They said 15 samples that 13 did show an asbestos mineral, only one exceeded 14 the estimated level. 15 Q. Chrysotile, if you find chrysotile, 16 that's asbestos; there's no dispute? 17 A. If it's been identified correctly, 18 yes. 19 Q. If you go to Table 1, they did X-ray 20 diffraction, right? 21 A. Correct. 22 Q. XRD is that one that has something 23 like one percent detection limit, half a percent 24 maybe down to .1, right? 25 A. Somewhere in that range, yes.</p>
<p style="text-align: right;">Page 79</p> <p>1 samples from the current ore body were also 2 examined"? 3 A. Correct. Again, this is all 4 Argonaut, but yes. 5 Q. No, the current ore body then was 6 Hammondsville. Argonaut was not yet approved until 7 '76. 8 A. Not approved for baby powder 9 production, yes. 10 Q. Not approved for anything, sir. 11 A. I'd have to check the records for 12 that. 13 Q. Okay. You don't know, do you? 14 A. Not with specificity. But whether or 15 not it was being used for other purposes, I believe 16 it was, but I would have to review the records since 17 you're challenging me -- 18 Q. I'll just ask you: I asked 19 Dr. Hopkins in this case, the jury has seen this, 20 that Argonaut was first approved in 1976. 21 Do you disagree with that? 22 A. I would have to look at the context. 23 Q. Here's all I want to ask you about is 24 they say that only one exceeded .0005 percent, 25 right?</p>	<p style="text-align: right;">Page 81</p> <p>1 Q. And they didn't find any asbestos mineral 2 using XRD. It's all over here. 3 Non-detect. One maybe chrysotile, correct? 4 A. That's correct. 5 Q. But, and actually Moshe just pointed 6 out to me, which he does sometimes, that they 7 actually state what their detection limit was in 8 here, so we don't have to speculate. 9 A. Oh, for the X-ray diffraction? Good. 10 Q. Yeah, for the XRD. 11 Here we go. "By XRD, in no instance 12 was any asbestos or potentially asbestos mineral 13 identified by XRD, the limit of whose sensitivity is 14 between half and one percent for amphibole and 15 probably slightly higher for this chrysotile 16 asbestos." Right? 17 A. You read that correctly. 18 Q. So when they get all those 19 non-detects, that's only credible down to about one 20 percent or so, at least in this report, right? 21 A. Yes. Of course. Any time you 22 analyze something, it's always within the scope of 23 what that analysis can tell you. 24 Q. Right. 25 When you are using a more powerful</p>

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<p>1 tool like electron microscopy, that's when they 2 actually got the hits for chrysotile and they also 3 found amphibole, correct?</p> <p>4 A. They do report both chrysotile and 5 amphibole detections.</p> <p>6 Q. All right.</p> <p>7 MR. PANATIER: Your Honor, good time 8 for a break?</p> <p>9 THE COURT: Yes.</p> <p>10 Members of the jury, we'll take the 11 morning break now. 15 minutes. Leave your 12 notebooks here.</p> <p>13 Remember my instructions: Do not 14 discuss this case, including the testimony you've 15 just heard. No research of any kind whatsoever.</p> <p>16 You may choose either all to stay up 17 here in the jury room or to go downstairs. You just 18 need to be in agreement.</p> <p>19 All right. So be ready to come back 20 up at quarter of. Thank you. Enjoy.</p> <p>21 (Jury exits.)</p> <p>22 THE COURT: Thank you, Dr. Sanchez. 23 You can step down.</p> <p>24 Thanks, everyone. Quarter of. 25 (Recess: 10:29 a.m. to 10:46 a.m.)</p>	<p>1 So I do have it up here. What is the 2 date on that one?</p> <p>3 Q. That's November 10, '71.</p> <p>4 THE COURT: For the record, what's 5 the exhibit number?</p> <p>6 MR. PANATIER: 2403.</p> <p>7 THE COURT: Thank you.</p> <p>8 BY MR. PANATIER:</p> <p>9 Q. And he very clearly is using electron 10 diffraction; he is getting patterns in this letter, 11 correct?</p> <p>12 A. In that letter, yes. It was the 13 other letter I was speaking to.</p> <p>14 Q. One of my items got out of order, so 15 I just wanted to ask you about it real fast. We 16 talked about some pamphlets that your company had 17 distributed for the Defense Research Institute.</p> <p>18 This will be Exhibit S-5.</p> <p>19 (S-5 was marked for identification.)</p> <p>20 BY MR. PANATIER:</p> <p>21 Q. Sir, you see this is a newsletter 22 from the American Industrial Hygiene Association?</p> <p>23 A. I see that.</p> <p>24 Q. You've seen this before, correct?</p> <p>25 A. I've been shown this before, yes.</p>
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<p>1 COURT OFFICER: Jury entering. 2 (Jury enters.)</p> <p>3 THE COURT: Please be seated. Make 4 sure cell phones are turned off.</p> <p>5 Mr. Panatier, whenever you're ready.</p> <p>6 MR. PANATIER: Thank you, your Honor.</p> <p>7 BY MR. PANATIER:</p> <p>8 Q. Dr. Sanchez, I just wanted to make 9 sure I understood what you said. Were you saying 10 that Dr. Langer was not getting diffraction patterns 11 on what he was looking at?</p> <p>12 A. Depending on the -- I'm sorry, excuse 13 me. When you look at the specific document, there 14 was one from '72 which was notes from somebody from 15 Johnson & Johnson going to go meet with him.</p> <p>16 Q. Okay.</p> <p>17 A. And that description, no, he was 18 simply looking at the external, the morphology of 19 the particles. He was not doing diffraction work.</p> <p>20 Q. Okay. So I just wanted to be clear. 21 Do you still have the letter that he sent them in 22 '71?</p> <p>23 A. That's not what I was thinking.</p> <p>24 Q. I understand.</p> <p>25 A. That's fine.</p>	<p>1 Q. And so it's a newsletter. If we go 2 to the second page, who's that guy?</p> <p>3 A. We've already seen that photo of me.</p> <p>4 Q. Okay. And it says, "As an industrial 5 forensics laboratory, we go beyond data delivery. 6 We provide solutions." Right?</p> <p>7 A. That's what it states.</p> <p>8 Q. So this is connect with an expert, 9 right?</p> <p>10 A. That's what it states.</p> <p>11 Q. Do you get residuals for any of 12 these, for anything?</p> <p>13 A. I don't know what that means.</p> <p>14 Q. I was making a joke. You know when 15 stuff gets published, do you get -- never mind. I'm 16 not very funny.</p> <p>17 A. No. I have no part in our marketing 18 efforts in the company and how they use my image.</p> <p>19 Q. Another document you talked about, 20 and this is Plaintiffs' Exhibit 2363 in evidence.</p> <p>21 Here you go, your Honor.</p> <p>22 Do you recall discussing the 23 Baby-Mate entry on the boards?</p> <p>24 A. I do.</p> <p>25 Q. And Mr. Dubin said that's not even</p>

<p style="text-align: right;">Page 86</p> <p>1 Johnson & Johnson, right?</p> <p>2 A. That's correct.</p> <p>3 Q. Let's see what they say. Okay.</p> <p>4 January 30, '67. Baby-Mate powder. They are</p> <p>5 investigating the Baby-Mate powder, correct?</p> <p>6 A. It appears so.</p> <p>7 Q. It says that "The talc base used in</p> <p>8 this product is better than 97 percent pure talc.</p> <p>9 The remainder is associated with carbonate and less</p> <p>10 than half a percent of fibrous -- of the fibrous</p> <p>11 tremolite."</p> <p>12 Right? So they're saying it's fibers</p> <p>13 of tremolite, correct?</p> <p>14 A. They report fibrous tremolite, yes.</p> <p>15 Q. And that means fibers of tremolite?</p> <p>16 A. Correct.</p> <p>17 Q. Okay. "This about compares with</p> <p>18 Italian Number 1 talc and is slightly less pure</p> <p>19 chemically than Ental EXTRA talc."</p> <p>20 Now, earlier today you brought up</p> <p>21 Italian Number 1. Italian Number 1 was the talc</p> <p>22 used by Johnson & Johnson, correct?</p> <p>23 A. I believe that is one of the names</p> <p>24 for it. Yes.</p> <p>25 Q. So it says this about compares with</p>	<p style="text-align: right;">Page 88</p> <p>1 correct?</p> <p>2 A. In the past, yes.</p> <p>3 Q. Imerys is the supplier of the raw</p> <p>4 talc and has been since 19 -- about 1989, 1990, to</p> <p>5 Johnson & Johnson?</p> <p>6 A. In one of its entity firms.</p> <p>7 Q. Right.</p> <p>8 It's been called Luzenac, it's been</p> <p>9 called Rio Tinto and so forth, right?</p> <p>10 A. Those are some -- some of the names,</p> <p>11 yes.</p> <p>12 Q. All right. Let me give you, this is</p> <p>13 Exhibit 3695-247.</p> <p>14 MR. DUBIN: We're going to have to</p> <p>15 approach about this.</p> <p>16 THE COURT: Sure.</p> <p>17 (Sidebar.)</p> <p>18 MR. DUBIN: This appears we're going</p> <p>19 to be cross-examining Dr. Sanchez with Imerys</p> <p>20 documents.</p> <p>21 At this phase of the trial, your</p> <p>22 Honor, the issue is what Johnson & Johnson should</p> <p>23 have known and understood. The cross-examining him</p> <p>24 with Imerys documents in a case with state of mind,</p> <p>25 I think, is improper.</p>
<p style="text-align: right;">Page 87</p> <p>1 the Italian talc that Johnson & Johnson was using,</p> <p>2 right?</p> <p>3 A. That's what it states.</p> <p>4 Q. And, in fact, they say, they're</p> <p>5 trying to determine the talc source and they say,</p> <p>6 "The structure of the particles, however, and the</p> <p>7 presence of the associated carbonates and tremolite</p> <p>8 lead me to believe this is an Italian talc, Robert</p> <p>9 Russell." Right?</p> <p>10 A. That's what it states.</p> <p>11 Q. So that would be the relation to</p> <p>12 Johnson's Baby Powder, wouldn't it; they're using</p> <p>13 Italian talc, correct?</p> <p>14 A. Again, what it says here, this guy</p> <p>15 doesn't know, he believes it may be an Italian talc.</p> <p>16 That's not saying it's Italian talc. We don't know</p> <p>17 what the source of Baby-Mate is.</p> <p>18 Q. But what he is saying is the</p> <p>19 percentage of fibrous tremolite, he says this about</p> <p>20 compares with Italian Number 1 talc which they were</p> <p>21 using, right?</p> <p>22 A. I think overall, that's what he says</p> <p>23 here.</p> <p>24 Q. Okay. Now, you also serve as an</p> <p>25 expert witness, or have in the past, for Imerys,</p>	<p style="text-align: right;">Page 89</p> <p>1 You've looked at this Imerys</p> <p>2 document, does that inform how you reviewed that</p> <p>3 document, then he would have to also rely on all the</p> <p>4 testing he personally has done because that</p> <p>5 similarly would inform how he read these documents.</p> <p>6 We've kept it to J&J notice issues. I think that's</p> <p>7 where it should be.</p> <p>8 MR. PANATIER: This is their</p> <p>9 supplier. Known or should have known, they asked</p> <p>10 the supplier, this is what they get. That's pretty</p> <p>11 clear.</p> <p>12 And this is -- I have two documents,</p> <p>13 or three, I have three. I have this one which</p> <p>14 covers Argonaut, still in Argonaut. Then I have two</p> <p>15 Chinese. And he's an expert for them and he's seen</p> <p>16 all of this. If he wants to try and say he hasn't</p> <p>17 seen it, that's fine, but he's seen all of it.</p> <p>18 And, again, counsel brought up all of</p> <p>19 the Chinese. He said we never had a positive</p> <p>20 result. But on knew or should have known, I think</p> <p>21 it's a pretty -- it's not attenuated to say if you</p> <p>22 ask your supplier, here's what you get.</p> <p>23 THE COURT: Thank you.</p> <p>24 Anything further?</p> <p>25 MR. DUBIN: Yes, your Honor. Then,</p>

<p style="text-align: right;">Page 90</p> <p>1 again, if he's permitted to go into this area and 2 wants to cross, the ideal is what he should be and 3 what should he (inaudible) looked at the products 4 themselves and (inaudible) asbestos and how is it 5 not relevant that (inaudible) he would have told us 6 there's no asbestos.</p> <p>7 So I feel like it's part and parcel, 8 we're getting far afield from what Johnson & 9 Johnson's state of mind.</p> <p>10 MR. PANATIER: One is regular 11 testing. The other is litigation testing. Quite 12 clear there's a delineation. Yesterday we got into 13 the regular routine testing with Dr. Sanchez and 14 this is the regular routine testing.</p> <p>15 THE COURT: Since Imerys or one of 16 its predecessors was a Johnson & Johnson supplier 17 and due to the fact that this is what Johnson & 18 Johnson either knew or should have known, this is 19 permissible cross-examination and I will allow it.</p> <p>20 MR. DUBIN: Will I be allowed to then 21 ask this doctor about his own testing, how that 22 relates to what he understands Johnson & Johnson 23 should have known?</p> <p>24 THE COURT: No. I mean, this is now 25 about the conduct of Johnson & Johnson. This is</p>	<p style="text-align: right;">Page 92</p> <p>1 yes, I have reviewed this.</p> <p>2 Q. This is Exhibit 3695, and you could 3 see that this is a summary of some testing that 4 Imerys did, correct?</p> <p>5 A. That's correct.</p> <p>6 Q. And you understand that Grade 66 is 7 the domestic baby powder powder and Grade 96 is what 8 they were selling to Canada, correct?</p> <p>9 A. From the Vermont source, yes.</p> <p>10 Q. Right.</p> <p>11 It's the same source, it just was 12 going International, Canada, right?</p> <p>13 A. I'm foggy on the details as I sit 14 here today. I can't verify that.</p> <p>15 Q. That's fine. Let's look at their 16 results. Chrysotile structures, you see that this 17 is the quarterly testing, right?</p> <p>18 A. For this time period, yes.</p> <p>19 Q. Okay. And you can see here that they 20 have one, two, three, four positive results for 21 chrysotile, correct?</p> <p>22 A. Correct. Observations of one fiber.</p> <p>23 Q. And this is by transmission electron 24 microscopy, they're looking at that super teeny tiny 25 amount of talc, right?</p>
<p style="text-align: right;">Page 91</p> <p>1 about the disclosures that were made on his report. 2 This does not open the door now to anything that was 3 not within his report that is proper at this phase.</p> <p>4 MR. DUBIN: I'm sorry, I understand. 5 I'll sit down. I just wanted to ask about that.</p> <p>6 THE COURT: Sure.</p> <p>7 MR. DUBIN: Obviously his testing is 8 in his report. We do think it's within the scope of 9 (inaudible) is aware historical documents 10 (inaudible). We'll make that proffer again. I 11 understand the court's ruling, so I can't do that 12 but I do want to make that proffer formally, but we 13 believe that's responsive to those issues.</p> <p>14 THE COURT: Thank you.</p> <p>15 Anything on that issue?</p> <p>16 Thank you. Let's continue.</p> <p>17 (Sidebar ends.)</p> <p>18 BY MR. PANATIER:</p> <p>19 Q. All right. Have you had a chance to 20 look at that?</p> <p>21 A. I have.</p> <p>22 Q. And you have reviewed that, as well 23 as probably thousands of Imerys documents? We have 24 a very long list you've been given.</p> <p>25 A. If this is a part of that list, then</p>	<p style="text-align: right;">Page 93</p> <p>1 A. That's correct.</p> <p>2 Q. And the analyst here has calculated 3 what the concentration would be of structures per 4 gram, correct?</p> <p>5 A. That's correct.</p> <p>6 Q. So just by finding one chrysotile 7 fiber here, that equates to, it's expressed in terms 8 of less than 132 million structures per gram, 9 correct?</p> <p>10 A. Ten to the sixth. I believe that's 11 accurate.</p> <p>12 Q. Okay. So when they find one here in 13 2002, that's approximately 133 million fibers per 14 gram, correct?</p> <p>15 A. No. It's less than 100 -- this is 16 one of those, in the noise of the measurement, but 17 again, they are reporting out their -- the 18 concentration that they can quantify to by -- with 19 the data and the method they're using is 133 million 20 structures per gram. What they're observing is less 21 than that.</p> <p>22 Q. Okay. Well, I think this might help 23 us. Look in the ones where they don't find 24 anything, right. They don't see any fibers there?</p> <p>25 A. Correct.</p>

1 Q. Their analytical sensitivity is 80 2 million fibers per gram, correct? 3 A. Well, again, you're calling this 4 analytical sensitivity. I believe this is a 5 detection limit, which is based upon a Poisson 6 distribution over the observed count. 7 Q. Right. 8 A. So the upper limit of your Poisson 9 would always -- would vary when you're in that 10 insignificant value. 11 Q. What this means is when they find 12 zero, all they can say is if it's present, it's 13 present at less than 80 million structures per gram, 14 correct? 15 A. They can't even say it's present. 16 They're saying this test certifies there is no 17 chrysotile detected or asbestos detected above that 18 detection limit. 19 Q. That's right. 20 A. That's all it says. 21 Q. That's right. 22 And the inverse is true, it's also 23 pointing out to say that it cannot draw conclusions 24 below 80 million structures per gram, correct? 25 A. Exactly. You cannot draw any	Page 94	Page 96
1 conclusion about what's in there below the method by 2 the test. 3 Q. Right. 4 Because if you don't have an 5 analytical sensitivity or detection limit that goes 6 below 80 million structures per gram, you cannot 7 draw conclusions one way or another as to what might 8 be in that concentration? 9 A. It would be improper to draw any 10 conclusion over what's there because you have no 11 information to say it's there. 12 Q. I gotcha. 13 But then we have these positives, 14 one, two, three and four, and there you can see the 15 concentration per gram jumps, doesn't it? 16 A. In this example, yes. 17 Q. And this would be saying, look, 18 there's something up to 132 million structures per 19 gram, correct? 20 A. No, it's saying the same thing. 21 Whatever they're calculating here, I don't know. I 22 need to see the full report. But whatever they're 23 calculating here, whether it's a -- appears to be a 24 detection limit to me, their detection limit is what 25 it is for the method based upon what the method	Page 95	Page 97

<p style="text-align: right;">Page 98</p> <p>1 present for you to see one?</p> <p>2 A. I don't think that's accurate.</p> <p>3 Q. That's what you just said.</p> <p>4 A. No, that's not what I said. I 5 disagreed with your characterization there.</p> <p>6 The issue is you look at the 7 detection, what that is. That detection there is, 8 what was it, 132 million fibers per gram, based on 9 the data they did for their analysis.</p> <p>10 Q. Um-hum.</p> <p>11 A. That's saying for every gram of talc, 12 that's their analytical sensitivity. It would be 13 less than whatever that 133 million would be. I 14 don't think that's what you said.</p> <p>15 Q. What I was saying pretty simply is, 16 if you look at, if you have a homogenized sample, 17 meaning everything is evenly distributed, and you 18 take one millionth of that sample and you find one 19 fiber, then scientifically you can say in order to 20 find that one fiber in a homogenized sample and I 21 only look at one million, there need to be a million 22 evenly distributed, correct?</p> <p>23 A. No, because again, you're confusing 24 particle counts with masses. So again, it doesn't 25 work that way.</p>	<p style="text-align: right;">Page 100</p> <p>1 this much asbestos by weight and there's one way to 2 say there's this much asbestos by particles?</p> <p>3 A. No. Particles by gram. There's 4 still a mass component to that calculation.</p> <p>5 Q. Right.</p> <p>6 It's how many particles in a gram, 7 right?</p> <p>8 A. Correct.</p> <p>9 Q. As opposed to how much asbestos 10 weight there is per gram, correct?</p> <p>11 A. Again, yes, a weight percent would be 12 mass by mass. Fibers per gram would be a particle 13 count per gram.</p> <p>14 Q. This is Exhibit 3695-253. This is 15 another Inerys document.</p> <p>16 MR. DUBIN: Same objection.</p> <p>17 THE COURT: Noted. Overruled.</p> <p>18 BY MR. PANATIER:</p> <p>19 Q. Can you see here, sir, Guangxi; this 20 is China now, right?</p> <p>21 A. That's correct.</p> <p>22 Q. And do you see here that under 23 chrysotile structures there's another hit in January 24 2003?</p> <p>25 A. I see that.</p>
<p style="text-align: right;">Page 99</p> <p>1 Q. I'm not, I'm asking you particle 2 counts.</p> <p>3 A. No. These reports -- the idea of it 4 being in there in a gram of talc, we still have that 5 mass component. So again, it depends on how -- 6 there's all sorts of ways you can calculate these. 7 We're getting lost in different ways to calculate 8 the same type of data.</p> <p>9 Q. Okay. I'm asking you to do -- by the 10 way, the ASTM D-5756 that you have utilized, the one 11 that did not become validated, remember that?</p> <p>12 A. That's not accurate. It was not -- 13 they didn't have validated information, so they 14 withdrew it.</p> <p>15 Q. Okay. Fine.</p> <p>16 That was a mass concentration method, 17 right?</p> <p>18 A. Yes. You would take your fiber 19 counts and then assign masses based on the size of 20 the particles and do a weight percent calculation.</p> <p>21 Q. And then there's D-5755, which is a 22 particle structure per gram?</p> <p>23 A. Correct. You do the same approach.</p> <p>24 It's just how you treat the end data.</p> <p>25 Q. There's one way is to say there's</p>	<p style="text-align: right;">Page 101</p> <p>1 Q. Okay. Then if you go to the very 2 next page, at the bottom, there's another hit for 3 chrysotile asbestos in November 2001, right?</p> <p>4 A. I see that.</p> <p>5 Q. Guangxi is where Johnson & Johnson 6 gets its talc, correct?</p> <p>7 A. Yes, for the U.S. market, yes.</p> <p>8 Q. All right. And then the last one of 9 these reports that we'll look at, sir, here, your 10 Honor, here you go, sir, this is 3695-252. And this 11 is a duplicate, just so we're clear, you see there's 12 right here, 3199-2?</p> <p>13 A. I see that.</p> <p>14 Q. And then the one I just handed you 15 has 3199-2?</p> <p>16 A. I see that.</p> <p>17 Q. That has the finding of the number of 18 structures, right?</p> <p>19 A. Correct.</p> <p>20 Q. The reason I'm giving you that is 21 because this one actually provides us with the count 22 sheet. And if you go to the very last page, that's 23 the one for the positive where they got 3199-2 and 24 they found the one structure, correct?</p> <p>25 A. Okay.</p>

<p style="text-align: right;">Page 102</p> <p>1 Q. Do you see that?</p> <p>2 A. I do.</p> <p>3 Q. First of all, we know the length and 4 width of this fiber, this fiber is, what is that, 5 14-to-1?</p> <p>6 A. It's .7 by .05. I think I would do 7 that on a calculator to make sure that was right.</p> <p>8 Q. Okay. That's fine.</p> <p>9 A. I think you're right, but just to 10 make sure.</p> <p>11 Q. 14.</p> <p>12 A. Thank you.</p> <p>13 Q. Here the analyst tells us, again, the 14 structure concentration in terms of structures per 15 gram, correct?</p> <p>16 A. Where are you looking now? I don't 17 see it here anymore. I have to turn around now.</p> <p>18 Okay. I want to make sure I'm looking at the same 19 place for what you're saying.</p> <p>20 Q. That's fine.</p> <p>21 A. So what was your question?</p> <p>22 Q. So my question is, again, the analyst 23 gives us the approximate structure concentration in 24 terms of structures per gram, correct?</p> <p>25 A. Correct.</p>	<p style="text-align: right;">Page 104</p> <p>1 Q. Rio Tinto, again, that's what later 2 became Imerys?</p> <p>3 A. That's correct.</p> <p>4 Q. Okay. And you've seen this document 5 before; correct, sir?</p> <p>6 A. Yes, I have.</p> <p>7 Q. Now, this is --</p> <p>8 MR. DUBIN: May we approach about 9 this document?</p> <p>10 THE COURT: Sure.</p> <p>11 (Sidebar.)</p> <p>12 MR. DUBIN: Johnson & Johnson 13 (inaudible) being asked about fibrous material 14 identify (inaudible) Dr. Sanchez was asked about 15 this these pictures (inaudible) what he reviewed 16 actual product, and we're really getting hamstrung 17 here having things --</p> <p>18 THE COURT: You already discontinued 19 use at Argonaut.</p> <p>20 MR. HYNES: (Inaudible).</p> <p>21 THE COURT: The purpose for which 22 you're seeking to use this document?</p> <p>23 MR. PANATIER: It goes to the fact 24 that he said that based on what's in Argonaut 25 there's -- nothing shows, they went through all</p>
<p style="text-align: right;">Page 103</p> <p>1 Q. And it says 202 million, correct?</p> <p>2 A. That's what it states.</p> <p>3 Q. Now, so that's Chinese talc. 4 I need to offer these.</p> <p>5 MR. PANATIER: Your Honor, we offer 6 3695-252, 253 and 247.</p> <p>7 MR. DUBIN: Objection based on what 8 we've discussed.</p> <p>9 THE COURT: Thank you.</p> <p>10 Objection is overruled. These are 11 now in evidence.</p> <p>12 (Plaintiff's Exhibit 3695-252 was 13 moved into evidence.)</p> <p>14 (Plaintiff's Exhibit 3695-253 was 15 moved into evidence.)</p> <p>16 (Plaintiff's Exhibit 3695-247 was 17 moved into evidence.)</p> <p>18 BY MR. PANATIER:</p> <p>19 Q. Sir, I'd like to show you another 20 document. This one is Rio Tinto, but that's the 21 same company, correct, or the same entity that was 22 supplying talc to Johnson & Johnson, right? Is that 23 right? Sorry, sir? Is that correct?</p> <p>24 A. I'm sorry. I was reading it. What 25 was your question?</p>	<p style="text-align: right;">Page 105</p> <p>1 yesterday. And this goes to show that had they, it 2 doesn't matter what the timing is, had they looked 3 in the Argonaut and had this analysis done, this 4 would have been the result on any date. That's the 5 point. It's there. It's a mine. It's millions and 6 millions of years old.</p> <p>7 MR. DUBIN: Your Honor, if the 8 question is had we looked at bottles from around 9 that time period or from the Argonaut mine and done 10 analysis on it would we have found this. This 11 expert knows from looking at the bottles themselves 12 what we would have found.</p> <p>13 THE COURT: That was relevant in the 14 compensatory phase and a jury determined that there 15 was asbestos in the product during the relevant time 16 frame and that it caused the mesothelioma of these 17 plaintiffs, so that issue is not in dispute. The 18 issue now is the conduct of Johnson & Johnson. So 19 what did Johnson & Johnson know or should have known 20 and what kind of testing they did. And you 21 established all of that on direct yesterday, the 22 kind of testing, what was known about the mines, 23 selective mining, all of that.</p> <p>24 So on cross-examination as to what's 25 known or what should have been known, this is</p>

<p style="text-align: right;">Page 106</p> <p>1 permissible cross-examination. To have him go 2 through his testing of the product, that was already 3 resolved by the prior jury. It's not the issue for 4 this jury.</p> <p>5 MR. DUBIN: I want to put one thing 6 on the record.</p> <p>7 THE COURT: Sure.</p> <p>8 MR. DUBIN: Your Honor, we disagree 9 that the jury's finding precludes us from responding 10 to something like this with this testing. Although 11 a jury may have found that at some point during the 12 period of exposure for these plaintiffs there was 13 some asbestos exposure, that does not mean that they 14 found at every point that there was asbestos 15 exposure or that they found material similar to this 16 in Johnson & Johnson's product. And we are being 17 precluded, we're now making an assumption that the 18 jury found at all times there was asbestos and that 19 there was this kind of material in the products made 20 from Argonaut in Johnson & Johnson, and we are -- we 21 would like to be able to respond to that with 22 evidence that Dr. Sanchez has tested products made 23 from ore sources from Argonaut and has not found 24 these kind of materials in them. And I have made my 25 statement.</p>	<p style="text-align: right;">Page 108</p> <p>1 millions and millions of years old, right? 2 A. I'm sorry?</p> <p>3 Q. What is in a deposit is millions and 4 millions of years old, billions?</p> <p>5 A. It can vary, but it would depend.</p> <p>6 Q. The earth is about 3.8 billion years 7 old, right?</p> <p>8 A. I think it's older than that.</p> <p>9 Q. Okay. All right. That's fair. It's 10 old?</p> <p>11 A. It is old, yes. That's correct.</p> <p>12 Q. These deposits are old?</p> <p>13 A. We're talking about Vermont here?</p> <p>14 Q. Yes.</p> <p>15 A. They are old deposits, but not as old 16 as the earth.</p> <p>17 Q. Okay. All right.</p> <p>18 Now, you see there's a sample, it 19 says, "Request." 3685-248. This is a sample of 20 acicular mineral material collected at the Argonaut 21 mine which was submitted for identification. And 22 the result was, "The sample was identified as 23 asbestosiform actinolite amphibole." Correct?</p> <p>24 A. That's correct.</p> <p>25 Q. That's asbestos?</p>
<p style="text-align: right;">Page 107</p> <p>1 THE COURT: Thank you.</p> <p>2 Whether or not asbestos was found in 3 every single bottle is not the issue, and because a 4 jury determined below that there was asbestos in the 5 product in sufficient quantities that it became a 6 substantial factor in the development of the 7 mesotheliomas. If we have testing or testimony by 8 Dr. Sanchez as to, well, these bottles or none of 9 the bottles I tested was it in there, then we get 10 into a second trial, a retrial of what happened 11 below, and let's bring Dr. Longo back and do that, 12 and that's not the issue in front of this jury.</p> <p>13 So your exception is noted. This is 14 permissible cross-examination. You may continue.</p> <p>15 (Sidebar ends.)</p> <p>16 BY MR. PANATIER:</p> <p>17 Q. All right. Did I give you a copy?</p> <p>18 A. Yes, I have a copy.</p> <p>19 Q. So this is from Julie Pier at Rio 20 Tinto/Imerys, the supplier.</p> <p>21 Now, in fairness, this report is five 22 years after Johnson & Johnson stopped using this 23 deposit, correct?</p> <p>24 A. Yes. This is from 2008.</p> <p>25 Q. Okay. But what is in a deposit is</p>	<p style="text-align: right;">Page 109</p> <p>1 A. Yes. This is clearly asbestos here.</p> <p>2 Q. These are SEM images, which are 3 scanning electron microscopy, correct?</p> <p>4 A. That's correct.</p> <p>5 Q. That first one, I don't know, can you 6 see the magnification on that one?</p> <p>7 A. This is a bulk sample, but it's 100 8 times.</p> <p>9 Q. That's 100. And then what's the 10 bottom picture?</p> <p>11 A. Appears to be -- it's a thousand 12 times.</p> <p>13 Q. All right. So they're not looking at 14 it at 20,000 times or anything like that. We're 15 getting a picture, a visual, of kind of what this 16 material looks like in its bulk state, correct?</p> <p>17 A. That's correct.</p> <p>18 Q. Now, let's chat about the test method 19 a little bit. You know what, one last thing on 20 Italian talc. This is the Paoletti paper that you 21 and Mr. Dubin talked about yesterday.</p> <p>22 Do you recall that?</p> <p>23 A. I do.</p> <p>24 THE COURT: What's the marking on it 25 for identification?</p>

1 MR. PANATIER: For identification, 2 this would be S-6. 3 THE COURT: Thank you. 4 MR. DUBIN: In evidence? 5 MR. PANATIER: I'm not going to 6 offer. 7 (S-6 was marked for identification.) 8 BY MR. PANATIER: 9 Q. All right. This is the paper that 10 you had discussed yesterday. "Evaluation by 11 electron microscopy from 1984, techniques of 12 asbestos contamination in industrial, cosmetic and 13 pharmaceutical talcs." 14 And one of the questions Mr. Dubin 15 asked you was, well, does this say anything about 16 Johnson's Baby Powder, and it doesn't say anything 17 about Johnson's Baby Powder directly? 18 A. That's correct. 19 Q. Okay. Typically in academic papers, 20 if a product is being studied, they typically don't 21 name the product? 22 A. I would think that would be accurate. 23 Yes. 24 Q. It can happen, but it doesn't happen 25 often; fair?	Page 110 1 Q. "29 different samples of talc for 2 industrial, cosmetic and pharmaceutical uses have 3 been analyzed; 15 from the Italian market and 14 4 provided by the European pharmacopeia from the 5 International market and from various geographic 6 areas." 7 So we're just going to focus on 8 Italian here. Okay? 9 A. Okay. 10 Q. And, of course, Johnson & Johnson was 11 using Italian talc for use in the United States 12 through the late '60s and then again in the early 13 '80s because of the mine strike. 14 Do you recall that? 15 A. That's my recollection. 16 Q. "To evaluate the pollution due to 17 asbestos in the studied talcs, the fibrous kinds of 18 amphiboles, tremolite and anthophyllite and the 19 fibrous kind of serpentine, chrysotile, have been 20 investigated." And then they refer us to a table. 21 "As reported in Table 7 through 9, in 22 eight out of the 15 Italian talcs the presence of 23 asbestos fibers has been revealed, in seven samples 24 there were fibers of tremolite and in one sample 25 there were fibers of chrysotile."
Page 111 1 A. Not normally, yes. 2 Q. Here, under introduction, it says, 3 "The most common minerals that may be found mixed 4 with talc in mineral deposits are listed in Table 1. 5 Among them, two fibrous kinds of amphibole, 6 tremolite and anthophyllite, and a fibrous kind of 7 serpentine mineral, chrysotile, constitute some of 8 the best known varieties of asbestos." 9 And I think you had told me earlier 10 that serpentine is the general category for 11 chrysotile, correct? 12 A. Serpentine is a mineral group name. 13 It's like an amphibole. You would then go from the 14 group into the individual species. So chrysotile is 15 part of the serpentine group. There's a bunch of 16 other ones as well. 17 Q. Right. 18 So serpentine would be the category 19 that chrysotile would be in? 20 A. It's a mineral group. Yes. 21 Q. Okay. If we go to results, page 227, 22 they say, "29 different samples" -- 23 A. I'm sorry. 227, you said? 24 Q. 227 on the top. There you go. 25 A. Okay.	Page 112 1 Right? That's what it says? 2 A. You read that correctly. 3 Q. And we could go to the tables. I 4 want to look at cosmetic and pharmaceutical. And 5 they said Table 7 through 9. So 7 is industrial 6 talc, they found some there. Then we go to 7 pharmaceutical. This is the Italian, correct? 8 A. These are samples out of the Italian 9 market, correct. 10 Q. Correct. 11 They found four out of five that 12 contained tremolite asbestos? 13 A. They are reporting tremolite fibers, 14 yes. 15 Q. Under what is the heading there? 16 A. Asbestos fibers, yes. I'm not 17 disagreeing with you. 18 Q. And for cosmetic talc, they found two 19 out of six to contain tremolite asbestos, correct? 20 A. That's correct. 21 Q. They even provide us some nice 22 pictures, right? There's a tremolite fiber, 23 correct, on Figure 4? 24 A. That's correct. That's what they 25 identify it as.

<p style="text-align: right;">Page 114</p> <p>1 Q. And Figure 5, you can see the 2 chrysotile fibers, right?</p> <p>3 A. It appears so. Yes.</p> <p>4 Q. Okay. Now, you're aware, sir, that 5 Johnson & Johnson was concerned about this article, 6 correct?</p> <p>7 A. I'm not aware of that.</p> <p>8 Q. This is Exhibit 3695-250. And the 9 reason I want to show this to you is because you had 10 said well, we don't know whether it has anything to 11 do with Johnson's Baby Powder. That's why I'm 12 showing it to you.</p> <p>13 Do you see this is a memo from 14 September 26, 1984, Johnson & Johnson?</p> <p>15 A. Yeah. Let me please read it first.</p> <p>16 Q. Sure. And this is in evidence 17 already. Go ahead and read it. Let me know when 18 you're ready.</p> <p>19 A. Okay.</p> <p>20 Q. And you see that Bill Ashton, William 21 Ashton states, "Attached is a copy," and he's 22 sending this to Talc de Luzenac; that's what later 23 became Imerys, right?</p> <p>24 A. Yes. Imerys was -- I'm sorry, what 25 was that question? I'm not following.</p>	<p style="text-align: right;">Page 116</p> <p>1 after the letter to Talc de Luzenac?</p> <p>2 A. Time-wise, yes.</p> <p>3 Q. Do you see that it's signed by the 4 same individual, Mr. Ashton?</p> <p>5 A. I see that.</p> <p>6 Q. If you turn to the second page, 7 please, sir, under talc --</p> <p>8 A. Can I have a chance to skim through 9 this? Sorry.</p> <p>10 Q. Of course. Sure. Sure.</p> <p>11 A. Okay. I read it.</p> <p>12 Q. Do you see where Mr. Ashton 13 references the Paoletti article again?</p> <p>14 A. I see that.</p> <p>15 Q. And he says, "I spoke to some of the 16 ASTM and ISO officials about the uncomfortable 17 business aspects of the recent Paoletti article 18 hoping they might have some ideas on how to 19 compromise it."</p> <p>20 Is that what he said?</p> <p>21 A. He did say that.</p> <p>22 Q. So what we know is that Paoletti put 23 out an article that addressed Italian talcs; true?</p> <p>24 A. Markets bought off of the Italian 25 market, yes.</p>
<p style="text-align: right;">Page 115</p> <p>1 Q. Luzenac is the entity that later 2 became Imerys?</p> <p>3 A. Yes. Imerys Talc bought some of the 4 talc deposits from Luzenac.</p> <p>5 Q. "Attached is a copy of a paper which 6 is very important to the talc industry in your 7 territory. It alleges that a substantial number of 8 talcs contain fibers and/or asbestos. It is 9 published by a reputable organization in Rome. It 10 has just appeared in this month's issue of 11 Regulatory Toxicology and Pharmacology here in the 12 states."</p> <p>13 And it references the article you and 14 I just looked at, right?</p> <p>15 A. It appears to.</p> <p>16 Q. So Mr. Ashton, from Johnson & 17 Johnson, says this paper comes from a reputable 18 organization, right, or published by a reputable 19 organization, correct?</p> <p>20 A. That's correct.</p> <p>21 Q. This is already in evidence. This is 22 3695-251. You see that? That is a memo, October 23 23rd, '84?</p> <p>24 A. I see that.</p> <p>25 Q. That's a little less than a month</p>	<p style="text-align: right;">Page 117</p> <p>1 Q. And that Mr. Ashton was aware of this 2 at Johnson & Johnson, correct?</p> <p>3 A. It appears so.</p> <p>4 Q. He said that it was published by a 5 reputable organization?</p> <p>6 A. He did.</p> <p>7 Q. And a couple weeks later, he said we 8 need to figure out ways to compromise it, correct?</p> <p>9 A. He was talking to these other 10 committee groups looking into it, whether it's 11 reasonable. But yes, that's the language he used.</p> <p>12 Q. Compromising?</p> <p>13 A. That's the language that was used.</p> <p>14 Q. Let's chat, I think this is the last 15 issue and then you and I will be finished. Let's 16 chat about Johnson & Johnson testing method 7024. 17 This is Defense 8393.</p> <p>18 So this is the test method that 19 Johnson & Johnson uses for transmission electron 20 microscopy, correct?</p> <p>21 A. This is their internal method, yes.</p> <p>22 Q. Okay. And the title is, Analysis of 23 Powdered Talc for Asbestiform Minerals by 24 Transmission Electron Microscopy. So what they're 25 trying to find is asbestos, correct?</p>

<p style="text-align: right;">Page 118</p> <p>1 A. Asbestiform minerals, yes.</p> <p>2 Q. Asbestiform minerals is a long way of 3 saying asbestos, right?</p> <p>4 A. Not entirely, but it can be used that 5 way.</p> <p>6 Q. Are they looking for asbestos or are 7 they not?</p> <p>8 A. They are, but there's other minerals 9 that can be asbestiform that aren't asbestos, so 10 there's just a nuance there.</p> <p>11 I'm not trying to disagree with you. 12 I'm just trying to be precise.</p> <p>13 Q. Okay. If we go to the page marked 3 14 of 6 or 5 of 9, however you like it.</p> <p>15 A. I'm there.</p> <p>16 Q. All right. A few things it says 17 here. First of all, I want to go to 9.0, 18 "Preparation time per sample, including preparation 19 of related materials, is one hour. Analysis search 20 time per sample is a maximum of two hours." Right?</p> <p>21 A. I see that.</p> <p>22 Q. So there's a top amount of time that 23 the analyst can actually spend on this if you're 24 following the method?</p> <p>25 A. I don't interpret it that way. This</p>	<p style="text-align: right;">Page 120</p> <p>1 Q. Yep.</p> <p>2 What this says here is "The detection 3 of five or more asbestiform minerals of one variety 4 in an analysis constitutes a quantifiable level of 5 detection. When no asbestiform minerals are 6 detected, a representative fiber size is used to 7 calculate a detection limit."</p> <p>8 Okay. So, what that means is, is 9 that in order to say that asbestos is present, you 10 have to have five or more fibers of any one type, 11 correct?</p> <p>12 A. In order to quantify how much is 13 present, yes.</p> <p>14 Q. Right.</p> <p>15 To say that, to report it as asbestos 16 present, quantifiable, correct?</p> <p>17 A. Correct. This is defining what the 18 statistical basis, what would be a level that you 19 could actually put a number on.</p> <p>20 Q. Because we've seen this. The jury 21 has seen this. Below quantifiable limit of 22 detection in a number of reports, right? That would 23 mean, in this context, that if you saw -- I'll 24 change colors so I don't get too confusing here.</p> <p>25 So if you saw four chrysotile fibers</p>
<p style="text-align: right;">Page 119</p> <p>1 is talking about routine, routine sampling and 2 analysis. This is what you'd expect, about an hour 3 to do it and no more than two hours to analyze it.</p> <p>4 Q. Okay. Under definition of a fiber, 5 it says, "An elongated particle with parallel sides 6 and an aspect ratio," that's length to width, 7 "3-to-1." Greater than or equal to 3-to-1, right?</p> <p>8 A. Correct.</p> <p>9 Q. "The definition employed may vary 10 with the needs of the client."</p> <p>11 And then it says you scan your grid 12 squares, et cetera, each asbestiform mineral is 13 recorded as to type, chrysotile, tremolite, 14 anthophyllite, et cetera, structure, whether it's a 15 bundle, a clump, a fiber and dimensions, length and 16 width. Right?</p> <p>17 A. That's correct.</p> <p>18 Q. It also has something that you have 19 brought up once or twice called the limit of 20 quantifiable detection, right?</p> <p>21 A. That's correct.</p> <p>22 Q. And what this says here --</p> <p>23 A. Which page are you on now?</p> <p>24 Q. 2 of 6. 4 of 9.</p> <p>25 A. 4 of 9. Thank you.</p>	<p style="text-align: right;">Page 121</p> <p>1 in this tiny, tiny, tiny bit of talc, you would 2 report it, you could report it as below quantifiable 3 limit of detection, correct?</p> <p>4 A. If the statistics you're using is a 5 five, what they're doing here, then yes.</p> <p>6 Q. And so I'm just asking you under the 7 method, that is how you could report it, correct?</p> <p>8 A. Yes.</p> <p>9 Q. If you had four anthophyllite fibers, 10 and this is all we're saying asbestos, we're not 11 saying anything else, if you had four anthophyllite 12 asbestos fibers, you could report below quantifiable 13 limit of detection, correct?</p> <p>14 A. According to the statistics, yes, 15 that would be a statistically valid way of reporting 16 results.</p> <p>17 Q. If you had four tremolite fibers, you 18 could report below quantifiable limit of detection, 19 correct?</p> <p>20 A. Same answer. Yes.</p> <p>21 Q. And lastly, if you had four 22 actinolite fibers, same answer, correct?</p> <p>23 A. That's correct.</p> <p>24 Q. So in practical terms, let's say 25 you've got your grid, right, and you're looking</p>

<p style="text-align: right;">Page 122</p> <p>1 down, you're looking in the -- you actually don't 2 look down in the TEM, you just look at a screen, 3 right?</p> <p>4 A. You do look at a screen, but you are 5 leaning forward.</p> <p>6 Q. Okay, leaning forward.</p> <p>7 A. It is projected below you, so...</p> <p>8 Q. Not in the eye pieces?</p> <p>9 A. At times you are, yes.</p> <p>10 Q. All right. Well --</p> <p>11 A. Again, I'm not trying to quibble.</p> <p>12 Q. That's fine. That's fine. Let's 13 just talk about how this method works.</p> <p>14 So you're looking in the view, and 15 typically you're looking at ten grid openings, 16 correct?</p> <p>17 A. I think if you follow this method, 18 yes, I think we're doing ten grid openings over two 19 grid preparations.</p> <p>20 Q. We talked about that yesterday; five 21 grid openings on two different hundred-space grids?</p> <p>22 A. Correct.</p> <p>23 Q. Let's say you're looking down and 24 your entire area that you looked at summarized in 25 this square, okay, and you have four, you see</p>	<p style="text-align: right;">Page 124</p> <p>1 your Honor.</p> <p>2 THE COURT: Thank you. Objection 3 noted. Overruled.</p> <p>4 Continue.</p> <p>5 A. What was your question? I'm sorry.</p> <p>6 Q. It's from Julie Pier?</p> <p>7 A. Yes, it is.</p> <p>8 Q. To Tim Hicks. And she's explaining 9 the detection limit on Johnson & Johnson's method, 10 correct?</p> <p>11 A. That's correct.</p> <p>12 Q. And she says -- thanks.</p> <p>13 She says, "Recently you asked for an 14 explanation of the reported detection limit of 15 method TM 7024 analysis of powdered talc for 16 asbestosiform minerals by TEM performed on Grade 66."</p> <p>17 That's the baby powder, right?</p> <p>18 A. Correct.</p> <p>19 Q. "The method states that the limit of 20 quantifiable detection is five fibers. In other 21 words, if only three fibers are detected, we could 22 say that the amount detected is below the 23 quantifiable detection limit." Right?</p> <p>24 A. Following the method, correct.</p> <p>25 Q. So under this method, the technician,</p>
<p style="text-align: right;">Page 123</p> <p>1 objectively, you see four fibers of chrysotile 2 asbestos, correct?</p> <p>3 A. It's all hypothetical. Okay.</p> <p>4 Q. Yeah. Under Johnson & Johnson's 5 method, you're allowed to report that as below 6 quantifiable limit of detection, correct?</p> <p>7 A. It would be below your ability to 8 quantify, yes.</p> <p>9 Q. Let's say you also see four fibers of 10 tremolite. Same answer, correct?</p> <p>11 A. That's correct.</p> <p>12 Q. And you also see four fibers of 13 actinolite. Same answer, correct?</p> <p>14 A. That's correct.</p> <p>15 Q. And you also see -- where's my green? 16 -- four fibers of anthophyllite, correct?</p> <p>17 A. Again, hypothetical, yes.</p> <p>18 Q. Well, in fact, sir, I've shown you 19 this before, this is 3695-249.</p> <p>20 Sir, you've seen that document 21 before, correct?</p> <p>22 A. I have.</p> <p>23 Q. And that is from Julie Pier, and she 24 worked at Imerys, right?</p> <p>25 MR. DUBIN: Same objection as before,</p>	<p style="text-align: right;">Page 125</p> <p>1 the analyst, can objectively see asbestos present in 2 the sample of baby powder and they are permitted, 3 under the method, to then put in the report below 4 the quantifiable limit of detection, correct?</p> <p>5 A. Based on the statistical uncertainty 6 chosen, yes.</p> <p>7 Q. Lastly -- yeah.</p> <p>8 So I'll offer that one I just used, 9 your Honor. 3695-249.</p> <p>10 MR. DUBIN: Same objection, your 11 Honor.</p> <p>12 THE COURT: Thank you. Noted. 13 Overruled. Now admitted into evidence.</p> <p>14 (Plaintiff's Exhibit 3695-249 was moved 15 into evidence.)</p> <p>16 BY MR. PANATIER:</p> <p>17 Q. And Moshe pointed out to me, he asked 18 me to go back to this, paragraph 8, background 19 correction. 'Cause I think you brought this up 20 yesterday that, I think you said, you know, early 21 on --</p> <p>22 A. I'm sorry. Which page are you on?</p> <p>23 Q. Sure. This is 3 of 6, 5 of 9.</p> <p>24 You said there was a time where 25 people expected more asbestos as a potential</p>

<p>1 contaminant, correct?</p> <p>2 A. In the past it was much more a</p> <p>3 problem from an environmental perspective, yes.</p> <p>4 Q. Okay.</p> <p>5 A. But you still have to determine your</p> <p>6 background levels within your laboratory and also</p> <p>7 within the analysis you're performing.</p> <p>8 Q. Yeah.</p> <p>9 What this says here is that, under</p> <p>10 background correction, "As of the time of this</p> <p>11 writing" -- and this is 1995 -- "background</p> <p>12 correction has not been necessary. The amount of</p> <p>13 background asbestos detected has been insignificant</p> <p>14 in comparison to the levels of asbestos found in</p> <p>15 contaminated samples."</p> <p>16 You're aware that's in there,</p> <p>17 correct?</p> <p>18 A. I am.</p> <p>19 Q. Okay. I want to take you back to the</p> <p>20 start of our conversation yesterday. And we have</p> <p>21 talked about the sensitivity of different methods,</p> <p>22 right?</p> <p>23 A. Correct. To some degree, but yes.</p> <p>24 Q. We've talked about how TEM as a tool</p> <p>25 can be more sensitive than light microscopy,</p>	<p>Page 126</p> <p>1 very, very small electron beam and it might go right</p> <p>2 past that big guy?</p> <p>3 A. It wouldn't be that way. The issue</p> <p>4 is the larger particles, you can't even look at</p> <p>5 them. I mean, your magnifications are -- you would</p> <p>6 never -- you don't use TEM to look at the big</p> <p>7 particles. You use TEM only to look at the fines.</p> <p>8 Q. You would be looking at a teeny</p> <p>9 little dot --</p> <p>10 A. Yes.</p> <p>11 Q. All right. So we talked about how,</p> <p>12 in each test, there's about .00002 grams that are</p> <p>13 actually evaluated. Can you tell me, in terms of</p> <p>14 actual weight, how many grams are actually analyzed</p> <p>15 in the ten grid openings that are looked at? Is it</p> <p>16 a millionth of a gram?</p> <p>17 A. I've never done the calculation.</p> <p>18 Q. It's less than this, right?</p> <p>19 A. Yes. It would be less than that.</p> <p>20 Q. Substantially less than that?</p> <p>21 A. It would be less than that.</p> <p>22 THE COURT: For the record, you're</p> <p>23 pointing at less than --</p> <p>24 BY MR. PANATIER:</p> <p>25 Q. Less than .00002 grams. Right?</p>
<p>1 correct?</p> <p>2 A. I think it's incorrectly to</p> <p>3 characterize it that way. It is better at looking</p> <p>4 at the -- it is able, it's sensitive from a particle</p> <p>5 size, it's more sensitive for a particle size</p> <p>6 aspect, yes.</p> <p>7 To know what those finest particle</p> <p>8 sizes are you have to use TEM. There's no other way</p> <p>9 to look at those. But as an overall sensitivity</p> <p>10 comparison you can do PLM analyses that would give</p> <p>11 you a much finer sensitivity than a TEM.</p> <p>12 But again, it's based upon what the</p> <p>13 analysis is and the scope of what it can and cannot</p> <p>14 do every time.</p> <p>15 Q. Let me ask a more simple question.</p> <p>16 TEM can see some things that the</p> <p>17 light microscope can't?</p> <p>18 A. And vice versa, yes. That's true.</p> <p>19 Q. Right.</p> <p>20 Like you said, if we've got this big</p> <p>21 fat fiber or bundle of fibers under PLM and I'm</p> <p>22 looking through this microscope, right, well, I</p> <p>23 could see that there?</p> <p>24 A. Yes.</p> <p>25 Q. But with TEM, we would be taking a</p>	<p>Page 127</p> <p>Page 129</p> <p>1 A. That's correct. It would be, it's</p> <p>2 less than that.</p> <p>3 Q. But let's say it was this. Let's say</p> <p>4 it was this amount that was being analyzed with</p> <p>5 every test.</p> <p>6 Now, I've asked you this before.</p> <p>7 Johnson & Johnson, generally speaking, starting in</p> <p>8 the mid '70s or so, was doing quarterly tests with</p> <p>9 TEM, correct?</p> <p>10 A. Quarterly composite testing, yes.</p> <p>11 Q. Right.</p> <p>12 And what that meant was, first of</p> <p>13 all, they would take, they would do J4-1 on every</p> <p>14 two silos, correct?</p> <p>15 A. I'd have to review the documents for</p> <p>16 the specific testing frequencies at that</p> <p>17 specificity.</p> <p>18 Q. Well, do you know how big their silos</p> <p>19 were?</p> <p>20 A. Not as I sit here today.</p> <p>21 Q. Okay. That's fine.</p> <p>22 They would do quarterly composite</p> <p>23 testing, which would mean that they would take, they</p> <p>24 would take kind of a mixture of things they had</p> <p>25 pulled over the quarter and they would test it one</p>

1 time? 2 A. That's correct. The material that 3 was being processed, they were taking, they were 4 taking samples and then compositing those samples 5 into a quarterly composite over that period. 6 Q. Right. 7 And they would do one TEM testing 8 each quarter, right? 9 A. I believe that's accurate. 10 Q. And then a later time came where they 11 went to doing biweekly TEM test, every two weeks, 12 right? 13 A. No, I think they changed the 14 frequency of their compositing to, from -- to a 15 biweekly composite. 16 Q. Okay. Let me just cut to the chase. 17 A. Thank you. 18 Q. You've reviewed a lot of documents; 19 Imerys documents, Johnson & Johnson documents. And 20 you and I have been through this before. 21 Overall, there are about, the last 22 time you and I talked about it, 365, but let's say 23 about 400 total TEM tests on Johnson & Johnson's 24 talc. 25 A. Okay.	Page 130	Page 132 1 Q. I'm going to put approx, approximate, 2 total talc tested. I'm going to put J&J talc, J&J 3 talc, by TEM is about .008 grams, right? That's 4 what our math was, right? 5 A. In your hypothetical, yes. 6 Q. Well, in my hypothetical I've 7 overestimated the amount that was actually studied 8 for each TEM test, haven't I? 9 A. Well, you're ignoring a few things, 10 but yes. Using the numbers that we just discussed, 11 that is the correct number. 12 Q. Right. 13 Now, when we talk about sensitivity 14 of different tests, I've asked you before, in really 15 kind of simple terms, we could say if you have a 16 bathroom scale, that's less sensitive than a 17 scientific scale, right? 18 A. Not -- again, depending on what you 19 need to weigh, you use different scales. That's the 20 way to look at it. 21 Q. Right. 22 A. So if you're trying to weigh your 23 weight of a person to a certain precision, you would 24 then choose a scale that would be appropriate to 25 measure that person to the precision you wish to
1 Q. Would you agree with that? 2 A. Somewhere in that ballpark. 3 Q. Okay. It's in the ballpark of 400 4 tests. So 400. And I'm going to put a little 5 baseball diamond there 'cause that's in the 6 ballpark. 7 Okay. Now, if we want to know how 8 much talc then has been evaluated, we could -- we 9 know the way less than this per test, the .00002, 10 but if we just took this and we wanted to ballpark 11 how much total asbestos -- total talc that Johnson & 12 Johnson has actually evaluated by TEM in terms of 13 weight, you just take that times that? 14 A. Well, you're going extrapolation, but 15 you could do it that way. 16 Q. I'm not talking about extrapolating. 17 I'm talking about the actual amount analyzed. 18 A. Sure. 19 Q. Okay. And we could do that. I still 20 have my calculator. We just multiply, right? 21 A. I believe that's accurate. Yes, I 22 believe that's correct. 23 Q. So it would be, if it's 400 tests, 24 400 times .00002 equals .008, right? 25 A. Grams, yes.	Page 131	Page 133 1 measure them. 2 Q. Not a bathroom scale. 3 A. That does not appear to be a bathroom 4 scale. 5 Q. This would be a scientific scale, 6 right? 7 A. It is a scale. Yes. 8 Q. Okay. Maybe you have a better one. 9 It's the Gemini 20. Is that any good, do you know? 10 A. I don't know anything about your 11 scale. But again, when we use scales, we always 12 calibrate them to know if they work or not. 13 So even with a scientific scale, you 14 still have to go through calibration of the unit. 15 Q. Okay. So this one is showing zero 16 and it's got this little guy. Do you know what this 17 is for? 18 A. I assume it's to check the weight. 19 Q. And it says 10G. Does that mean ten 20 grams? 21 A. That's correct. 22 Q. So if you put this on here, it should 23 give us close to ten grams. Oops. Sorry. 24 10.01415. So it's very, very close, 25 correct? Can you see that?

<p style="text-align: right;">Page 134</p> <p>1 A. I see that. 2 Q. Sorry. This thing kind of -- 3 A. You shaded it at one point. I think 4 it helped. 5 Q. Oh, light. Okay. That helps. Okay. 6 We see that it's -- there. If I 7 shadow it, we're very close to 10 grams. Okay? 8 A. Don't move. 9 Q. Okay. So we're going to take that 10 off. And actually I think it's got this feature 11 called tare or tare, and if we press that I think 12 that zeros us out. Okay. Never mind. 13 Okay. We're back to zero. Okay. So 14 here's where I'm going. Total amount of talc tested 15 by TEM by Johnson & Johnson. If we want to know if 16 that's less than the weight of one of these Ice 17 Breaker breath mints, we can just weigh it, right? 18 A. That's true. 19 Q. So an Ice Breakers brand breath mint 20 weighs about 8/10ths or thereabout of a gram, would 21 you say? 22 A. That one does, yes. 23 Q. This one does. 24 And so a mint weighs .8 grams and we 25 have these convenient 8s here. How much heavier is</p>	<p style="text-align: right;">Page 136</p> <p>1 I doubt I'll finish before lunch, so 2 what time would your Honor like me to go until? 3 THE COURT: No later than one 4 o'clock. 5 MR. DUBIN: It won't matter to me to 6 stop, so I'll just pick whenever. I'll see when 7 people look hungry. 8 REDIRECT EXAMINATION BY MR. DUBIN: 9 Q. All right. Hi, Dr. Sanchez. How are 10 you? 11 A. I'm well. 12 Q. So I want to start with one of the 13 questions that you were asked early on about these 14 boards. Okay? And the question you were asked is 15 whether the boards are accurate, right? 16 You recall that? 17 A. From Mr. Panatier? 18 Q. Right. 19 A. Yes. I recall. 20 Q. And in that sense, if we look in 21 these documents can we find these words there, 22 right? 23 A. Yes, we can. 24 Q. But if we want to talk about these 25 boards as a whole, if someone were to suggest that</p>
<p style="text-align: right;">Page 135</p> <p>1 that mint than the total amount of talc that Johnson 2 & Johnson, by our discussions, has tested by TEM? 3 A. It would be 100 times more. 4 Q. 100 times. 5 A. Two orders of magnitude. 6 Q. So if we wanted to visualize for our 7 jury that amount, we would have to take this mint 8 and we would divide it by a hundred times, 9 correct? 10 A. No. The density of the mint and the 11 density of the talc are different, so you wouldn't 12 be -- the volumes wouldn't be the same. 13 Q. I'm not talking about cutting it into 14 tiny pieces. We would take 1/100th of this mint? 15 A. To do what? 16 Q. In terms of weight. 17 A. For weight perspective, yeah. 18 Q. We would take 1/100th of the mint to 19 get .008 grams, right? 20 A. Yes. 21 MR. PANATIER: Those are all the 22 questions I have. 23 THE COURT: Thank you. 24 Redirect? 25 MR. DUBIN: Yes, thank you.</p>	<p style="text-align: right;">Page 137</p> <p>1 these boards represent actually scientific valid 2 findings of asbestos in Johnson & Johnson's 3 products, would that be accurate? 4 A. No, it would not be. 5 Q. Okay. And we talked a lot about this 6 yesterday, but I want to go through some of the 7 documents that you were shown and discuss them. 8 One thing that you were asked about 9 fairly early on was Dr. Pooley's report. And what 10 the plaintiffs showed you, I'm truly awful about 11 this, is a section of a very long report that he 12 wrote regarding, a section of a very long report 13 that he wrote about his mine visit in Italy. 14 And just even looking at the document 15 itself, they read to you this part. It says, 16 "Particles formed from the amphibole mineral found 17 at the mine were hardly fibrous in character, the 18 majority of the tremolite breaking to give compact 19 particles. Those fibers formed were short and had a 20 very large diameter when compared with the 21 commercial varieties of asbestos." 22 You see that? 23 A. I do. 24 Q. And I'm going to come back to that, 25 but first I'd just like to point out what</p>

<p>1 plaintiffs' counsel did not read in the next 2 sentence from this document.</p> <p>3 What does it say?</p> <p>4 A. You want me to read it?</p> <p>5 Q. Yeah.</p> <p>6 A. "No amphibole or chrysotile mineral 7 was detected in any of the numerous powders 8 examined."</p> <p>9 Q. So here he's talking about the mine 10 site, right?</p> <p>11 A. Yes.</p> <p>12 Q. Is there any question about whether 13 Dr. Pooley, in the very document they asked you 14 about, whether he said -- what did he say about 15 whether there was asbestos in any of the Johnson & 16 Johnson powders?</p> <p>17 A. Well, the powders he tested here, he 18 says they were not detecting any asbestosiform 19 minerals in those powders.</p> <p>20 Q. Was there any asbestos in any of the 21 Johnson & Johnson product that he evaluated?</p> <p>22 A. Not to my recollection.</p> <p>23 THE COURT: Counsel, for the record, 24 you're going to need to identify that.</p> <p>25 MR. DUBIN: Sorry. This was the</p>	<p>Page 138</p> <p>1 Q. And in terms of whether Dr. Pooley 2 actually did think there was asbestos in those 3 samples, there was a cover letter for that report, 4 right?</p> <p>5 A. There was.</p> <p>6 Q. And we looked at that cover letter 7 yesterday, Dr. Pooley writing to Dr. Shelley at 8 Johnson & Johnson. And what did he conclude 9 about -- what did he tell Johnson & Johnson about 10 whether there was asbestos in that Italian mine they 11 were using?</p> <p>12 A. He says, "No chrysotile was found at 13 the mine or in the samples taken. Some tremolite 14 was located, but was not asbestosiform in character 15 and has not been detected in the 00000 talc imported 16 into Great Britain for the past year, nor in 17 shipments dating back to 1949. I hope that it is of 18 some interest to you."</p> <p>19 Q. And despite Dr. Pooley saying that, 20 is that entry on plaintiffs' board of J&J's internal 21 documentation in this case having to do with 22 asbestos?</p> <p>23 A. No.</p> <p>24 Q. Is it listed on their board?</p> <p>25 A. It is on their board.</p>
<p>1 document that they had used. It was part of Defense 2 8372.</p> <p>3 THE COURT: Thank you.</p> <p>4 MR. DUBIN: No problem.</p> <p>5 BY MR. DUBIN:</p> <p>6 Q. And let's just assume for a second 7 that we're going back again to see whether it was 8 true or not. Let's assume, let's go with the 9 plaintiffs' idea that somehow this document says 10 there's asbestos in Johnson & Johnson. Okay? 11 Forget what we just talked about for one minute. 12 Okay?</p> <p>13 A. Okay.</p> <p>14 Q. We went through this yesterday, and 15 this is a slide made from admitted exhibit, Defense 16 8372.</p> <p>17 Who did Johnson & Johnson give that 18 very same Pooley report to that we were just looking 19 at?</p> <p>20 A. This was part of their submission to 21 the FDA at this time.</p> <p>22 Q. So this very document that they 23 cross-examined you about and said that it found 24 asbestos, who did Johnson & Johnson give it to?</p> <p>25 A. The FDA.</p>	<p>Page 141</p> <p>1 Q. Is that a finding of asbestos?</p> <p>2 A. It is not.</p> <p>3 Q. And then you were asked a little bit 4 about Dr. Pooley's testimony, and again, that's not 5 something you've reviewed.</p> <p>6 Just to put it in context a little 7 bit, this was the deposition that he was talking 8 about, just to show you some additional parts of it, 9 talking about looking at the batches of talc and old 10 samples, "What did you conclude after looking at 11 those shipments and all the various samples? No 12 fibrous asbestos minerals detected."</p> <p>13 So that's something that you weren't 14 shown from Dr. Pooley's deposition?</p> <p>15 Do you see that?</p> <p>16 A. I do.</p> <p>17 Q. Okay. And he was also asked, "And do 18 you believe that all the testing that indicated 19 there's no asbestos in Johnson & Johnson's talc are 20 conclusions that, as you're sitting here today 21 looking at all this material, do you stand by the 22 work that you did?"</p> <p>23 And what was his answer?</p> <p>24 A. "Yes."</p> <p>25 Q. Again, so is it important in some of</p>

1 these contexts to look at some additional 2 information? 3 A. It's always good to have more 4 information. 5 Q. And when I say whether all of these 6 findings were, represent scientifically valid, you 7 know, one of the other ones I thought was very 8 interesting we didn't go back to with -- plaintiffs' 9 counsel didn't go back to is this Dutch Consumer 10 Organization. I want to talk about that. 12/13/73. 11 MR. PANATIER: Your Honor, that's 12 beyond the scope. 13 THE COURT: Sidebar. 14 (Sidebar.) 15 THE COURT: It does seem to exceed 16 the scope of cross-examination. 17 What's the purpose? 18 MR. DUBIN: Yes. He asked the 19 witness, your Honor, are these boards accurate, 20 right. And so he put into play the accuracy of the 21 boards. And now I'm trying to explain the witness's 22 answer when he said it was accurate, what it meant 23 and what it didn't mean, these board entries. He 24 asked about the boards in their entirety and then 25 I'm going into that very same issue.	Page 142 1 Organization, 12/13/73, that says the word asbestos? 2 A. Yes. 3 Q. Does that mean that the Dutch 4 Consumer Organization, in fact, found asbestos in 5 Johnson & Johnson's product? 6 A. No. It does not. 7 Q. And we looked at an issue like this. 8 This is one of the examples we looked at yesterday. 9 Can you remind the jury what the 10 problem was with what the Dutch Consumer 11 Organization did? 12 A. Yes. Their definition of asbestos 13 would include talc. Any mineral that would have 14 magnesium and silicate in it like talc, if it had an 15 elongated or needle form would be called asbestos 16 under that method. 17 Q. And so is it any surprise that the 18 Dutch Consumer Organization could find talc in 19 talcum powder? 20 A. No. Again, you would -- in any 21 talcum powder sample you will find some fibrous 22 talc. You will see talc that are elongated, that 23 have a fiber shape. In any talc you look at you 24 will find those. 25 Q. Is it an accurate characterization to
1 THE COURT: Thank you. 2 Yes? 3 MR. PANATIER: I asked him if the 4 boards, if what is reported on the boards is in the 5 documents and he said yes. Now he's trying to get 6 into the substance of the board. I didn't talk 7 about the Dutch Consumer Organization. 8 THE COURT: He's using it by way of 9 an example. 10 How many of these ways of example are 11 you doing? 12 MR. DUBIN: Most of them focus on 13 specific documents that he did instead of other 14 ones. I don't think I have -- 15 THE COURT: Okay, fine. 16 (Sidebar ends.) 17 BY MR. DUBIN: 18 Q. So again, the reason I'm asking this 19 is 'cause he asked you whether the boards were 20 accurate, so I'm just trying to put in context your 21 response. Otherwise, I'll talk more about specific 22 documents he raised. 23 Just as an example, you were asked 24 were the boards accurate. And is it accurate that 25 there's a document from the Dutch Consumer	Page 143 Page 145 1 somehow say that that's a finding -- internal 2 documentation by J&J of a finding of asbestos in 3 this product? 4 A. No. That would be incorrect. 5 THE COURT: Counsel, for the record, 6 what was that? 7 MR. DUBIN: I'm sorry. The document 8 that I'm displaying right now is Defense 7070 9 admitted. 10 THE COURT: 77 what? 11 MR. DUBIN: I'm sorry, 7070 admitted. 12 THE COURT: Thank you. 13 BY MR. DUBIN: 14 Q. So let me focus on some of the 15 documents you were specifically asked about then, 16 because I don't want to repeat myself. 17 So one of the documents you were 18 asked about also, and we'll talk a little bit more 19 about the whole Lewin thing, but you were asked 20 about this analysis of Italian medicated Grantham 21 talc from Rolle's files that includes also 22 discussion of Lewin Shower to Shower. 23 You see here where it says that 24 there's a finding of rod or needle tremolite? Does 25 that mean that's asbestos?

<p>1 A. Not necessarily. No.</p> <p>2 Q. And we know that also if we look at</p> <p>3 what the FDA found --</p> <p>4 THE COURT: Counsel, I don't want to</p> <p>5 interrupt you, but --</p> <p>6 MR. DUBIN: I am just assuming the</p> <p>7 plaintiffs --</p> <p>8 THE COURT: No. You're creating a</p> <p>9 record. The record can't see what was said.</p> <p>10 MR. DUBIN: I understand. It's 3441,</p> <p>11 Plaintiffs' Exhibit.</p> <p>12 THE COURT: Thank you.</p> <p>13 BY MR. DUBIN:</p> <p>14 Q. And then if we look at what we looked</p> <p>15 at yesterday, this D-8869, this whole idea about</p> <p>16 tremolite and tremolite being found in the 1970s,</p> <p>17 what does this show about whether the FDA was aware</p> <p>18 of tremolite, that tremolite could be in talc dating</p> <p>19 all the way back into the 1970s?</p> <p>20 MR. PANATIER: Your Honor, I object</p> <p>21 to this on outside the scope and I have more</p> <p>22 actually, I mean, sidebar.</p> <p>23 THE COURT: Sure.</p> <p>24 MR. PANATIER: Sorry.</p> <p>25 THE COURT: Can you take that down,</p>	<p>Page 146</p> <p>1 otherwise, that confuses the jury.</p> <p>2 Listen, I let you do the one as an</p> <p>3 example, but if you're going to use that, you're</p> <p>4 going to have to tell the jurors that this was not</p> <p>5 the document that was referenced or not the test</p> <p>6 that was referenced by counsel. That's fair.</p> <p>7 MR. DUBIN: I understand that.</p> <p>8 THE COURT: You have a choice.</p> <p>9 MR. DUBIN: Okay. I'm fine to</p> <p>10 identify, that's fine.</p> <p>11 THE COURT: Right. But then not</p> <p>12 exceeding the scope means not exceeding the scope.</p> <p>13 MR. DUBIN: I understand.</p> <p>14 THE COURT: That's what it means in</p> <p>15 this jurisdiction.</p> <p>16 MR. DUBIN: I understand, your Honor.</p> <p>17 As I articulated, I am trying to stay within the</p> <p>18 scope. I will be mindful of your Honor's</p> <p>19 admonishments.</p> <p>20 THE COURT: You're going to stay</p> <p>21 within the scope.</p> <p>22 MR. PANATIER: I didn't even use the</p> <p>23 document, by the way. I just asked him a question.</p> <p>24 THE COURT: He's allowed to use the</p> <p>25 document if it was a document that you referenced.</p>
<p>1 please?</p> <p>2 (Sidebar.)</p> <p>3 MR. PANATIER: So it's scope. I</p> <p>4 asked him about Sample 84. The FDA, in the '70s,</p> <p>5 found asbestos in Sample 84, 107,000 fibers per</p> <p>6 gram, and he said yes and I moved on. This now he's</p> <p>7 putting up some other samples of 196 which he did</p> <p>8 yesterday. It's outside the scope. Again, it's not</p> <p>9 part of this.</p> <p>10 THE COURT: Sorry. I thought I was</p> <p>11 going to sneeze.</p> <p>12 MR. PANATIER: Bless you.</p> <p>13 MR. DUBIN: Your Honor, we're trying</p> <p>14 to put the documents that he used with the witness</p> <p>15 in cross in context that this idea of somehow</p> <p>16 Johnson & Johnson is finding tremolite, some hidden</p> <p>17 (inaudible) with the FDA. I'm simply putting his</p> <p>18 document into context quickly.</p> <p>19 You know, his idea of scope is</p> <p>20 incredibly tight at this point as if I can only ask</p> <p>21 about the precise document that he puts on the</p> <p>22 screen whether there's a topic.</p> <p>23 THE COURT: That's generally what</p> <p>24 scope means. I'm not going to allow it. If you</p> <p>25 have a question about that precise document, but</p>	<p>Page 147</p> <p>1 MR. PANATIER: Sure. And that's not.</p> <p>2 THE COURT: That would be within the</p> <p>3 scope. Stay within the scope.</p> <p>4 (Sidebar ends.)</p> <p>5 BY MR. DUBIN:</p> <p>6 Q. We just showed a document about the</p> <p>7 internal discussion of tremolite at Johnson &</p> <p>8 Johnson.</p> <p>9 Have we also discussed documents, and</p> <p>10 plaintiffs' counsel discussed them with you, showing</p> <p>11 that the FDA was aware, in the 1970s, that there</p> <p>12 could be tremolite in cosmetic talcs?</p> <p>13 A. Yes.</p> <p>14 Q. And so I want to talk a little then</p> <p>15 about the documents that you went through with</p> <p>16 Dr. -- about Dr. Lewin, and this was one of the</p> <p>17 first ones that the plaintiff showed you. It's</p> <p>18 Plaintiffs' Trial Exhibit 2852, or it would be if we</p> <p>19 could see it.</p> <p>20 And so we all understand where we</p> <p>21 are, sometime in the early 1972, Dr. Lewin claimed</p> <p>22 to find asbestos in a number of different products,</p> <p>23 primarily by using a technique called XRD, right?</p> <p>24 A. Yes.</p> <p>25 Q. And then again, to provide some</p>

<p style="text-align: right;">Page 150</p> <p>1 context to that, we talked about the fact that, and 2 this we discussed yesterday, just to provide a 3 little historical context, Defense 7073, what 4 happened after Dr. Lewin made those initial claims?</p> <p>5 A. Again, there was a lot of research 6 that was done about what was found and whether that 7 was accurate or not.</p> <p>8 Q. And we also, again, for context, went 9 through this, Defense 9262. And what ultimately was 10 the conclusion about whether those initial 11 allegations by Dr. Lewin were correct or not?</p> <p>12 A. Again, this is Walter C. McCrone 13 speaking here. He calls that the original report 14 was grossly wrong.</p> <p>15 Q. Okay. And you were asked 16 specifically about some of the testing that was 17 done, you know, he put up on the board the specific 18 ones that were done by XRD, right?</p> <p>19 A. Correct.</p> <p>20 Q. And can you remind the jury why 21 Johnson & Johnson was having certain experts look at 22 Dr. Lewin's findings by using the technique XRD?</p> <p>23 A. Yes. At that time, Lewin was using 24 powder X-ray diffraction and claiming to find 25 asbestos. So Johnson & Johnson went to experts in</p>	<p style="text-align: right;">Page 152</p> <p>1 about whether Dr. Lewin was right?</p> <p>2 A. It says, "The above data does" -- 3 this is speaking, again, to x-ray diffraction data. 4 "The above data does not indicate the presence of 5 chrysotile."</p> <p>6 Q. We looked at experts from Carnegie 7 Mellon. That was Defense 8372 --</p> <p>8 MR. PANATIER: Your Honor, scope and 9 leading, your Honor.</p> <p>10 THE COURT: Scope is fine. Just 11 don't lead.</p> <p>12 MR. DUBIN: I'm just asking did -- 13 okay.</p> <p>14 BY MR. DUBIN:</p> <p>15 Q. Did we look at this document 16 yesterday?</p> <p>17 A. We did.</p> <p>18 Q. 8372?</p> <p>19 A. Sorry. We did.</p> <p>20 Q. And I don't think what did they find 21 is leading; what did they find?</p> <p>22 A. Again, looking at the X-ray 23 diffraction information, he agrees there is no 24 positive evidence for the presence of chrysotile in 25 the Shower to Shower product.</p>
<p style="text-align: right;">Page 151</p> <p>1 the field of powder X-ray diffraction to have them 2 evaluate those results and test samples by that same 3 methodology to see what they were seeing.</p> <p>4 Q. And again, these were written up on 5 the board by plaintiffs' counsel, so let's again 6 look at what people actually concluded.</p> <p>7 We looked at Defense 8372 with this 8 expert from M.I.T., and what was he saying about 9 Dr. Lewin's findings?</p> <p>10 A. He says, "My conclusion is that no 11 tenable evidence has been advanced to show that any 12 Johnson & Johnson product was made with talc which 13 contains chrysotile asbestos, and no tenable 14 evidence has been advanced to show that the product 15 as sold and manufactured contains chrysotile 16 asbestos."</p> <p>17 Q. And we looked at this conclusion from 18 Dr. Gordon that they asked you about on 19 cross-examination. This was Defense 8372. And did 20 he conclude whether there was asbestos or not?</p> <p>21 A. Based on the X-ray diffraction 22 testing, he says no evidence for chrysotile or 23 tremolite was found.</p> <p>24 Q. We looked at the Colorado School of 25 Mines, Defense 8372, and what did they conclude</p>	<p style="text-align: right;">Page 153</p> <p>1 Q. And so we've now talked about some 2 XRD analysis, and I want to talk about the other 3 document that plaintiffs asked you about, about 4 this.</p> <p>5 THE COURT: For the record.</p> <p>6 BY MR. DUBIN:</p> <p>7 Q. This was a document, Plaintiffs' 8 Trial Exhibit 2424, and it was a summary of a FDA 9 meeting back in, I think that's August 11, 1972 -- 10 1972, and one of the things they focused on with you 11 is this.</p> <p>12 So again, the plaintiffs' counsel 13 asked you about what was being done to verify 14 whether or not Dr. Lewin's results were correct.</p> <p>15 Do you recall that discussion?</p> <p>16 A. I do.</p> <p>17 Q. And two parts of this document were 18 highlighted. I want to focus on the first with you.</p> <p>19 It says, "In subsequent discussion, 20 Mr. Ian Stewart pointed out that light microscopy 21 may not detect chrysotile fibers."</p> <p>22 You see that?</p> <p>23 A. I do.</p> <p>24 Q. And so what's going on there?</p> <p>25 A. The proposal of Dr. Lewin to look at</p>

<p style="text-align: right;">Page 154</p> <p>1 his results to try to do some verification work was 2 to go to the optical microscopy, to use optical 3 microscopy. Ian Stewart of McCrone rightly points 4 out there is a chance, using only optical, that some 5 of the find -- fine fibers of chrysotile present, 6 you wouldn't be able to see them.</p> <p>7 Q. And so, if I am framing this wrong 8 correct me, but was one of the criticisms that 9 plaintiffs' counsel was making is that they 10 shouldn't have been using optical microscopy to 11 verify whether Dr. Lewin is right?</p> <p>12 A. Say that again. I'm sorry.</p> <p>13 Q. I think there was a suggestion that 14 you shouldn't be using optical microscopy to verify 15 whether Dr. Lewin was right or not because of what 16 Dr. Stewart said.</p> <p>17 A. No. I don't think -- optical 18 microscopy isn't bad for this, especially at the 19 ranges that Dr. Lewin is reporting, two or three 20 percent. But there is always the chance if you do 21 have some, a little bit in there and it's only in 22 the fines, you wouldn't be able to see it by PLM. 23 So there's nothing wrong with what 24 he's saying here, it's correct.</p> <p>25 Q. Let's also just say hypothetically,</p>	<p style="text-align: right;">Page 156</p> <p>1 Johnson actually did, we looked at this document 2 yesterday --</p> <p>3 THE COURT: Again, for the record.</p> <p>4 MR. DUBIN: Defense 8372.</p> <p>5 BY MR. DUBIN:</p> <p>6 Q. In evaluating whether Dr. Lewin's 7 findings were correct, did Johnson & Johnson do more 8 than having its consultants look at the samples with 9 optical microscopy?</p> <p>10 A. Yes, they did.</p> <p>11 Q. What else did they have them do?</p> <p>12 A. Again, they were doing -- they had 13 their consultants look powder X-ray diffraction, 14 which we just talked about, they had electron 15 microscopy conducted and in some cases, some optical 16 microscopy was also conducted.</p> <p>17 Q. So did Johnson & Johnson have its 18 experts do more, less or the same amount of work to 19 verify these allegations than the FDA was 20 suggesting?</p> <p>21 A. I think Lewin was suggesting it at 22 that point, but they were doing more than what was 23 suggested by Lewin to verify his findings.</p> <p>24 Q. And in that respect, is that in any 25 way comparable to what Johnson & Johnson did in its</p>
<p style="text-align: right;">Page 155</p> <p>1 hypothetically, if Mr. Stewart from McCrone wanted 2 the FDA to miss asbestos if it's there, to not find 3 it if it's there, is there any reason to tell them 4 this?</p> <p>5 A. You want me to assume that Mr. Ian 6 Stewart would not want the FDA to find asbestos?</p> <p>7 Q. Right. If that was their motive.</p> <p>8 A. Okay.</p> <p>9 Q. So is that something they would say?</p> <p>10 A. I don't think somebody would say that 11 if that was their motive.</p> <p>12 Q. Are they telling the FDA maybe you 13 should use a different method if you want to really 14 find it?</p> <p>15 A. Say that one again, I'm sorry.</p> <p>16 Q. What are they advising the FDA you 17 should do?</p> <p>18 A. He's raising the concern that only 19 using light microscopy, you could miss if there were 20 chrysotile fibers.</p> <p>21 Q. So what kind of microscopy would you 22 then use if you had that concern?</p> <p>23 A. At this point, transmission electron 24 microscopy.</p> <p>25 Q. So if we look then at what Johnson &</p>	<p style="text-align: right;">Page 157</p> <p>1 routine testing for cosmetic talc?</p> <p>2 A. As I've stated in my direct 3 testimony, they always went beyond the industry 4 standard.</p> <p>5 Q. And was McCrone, this is Defense 6 8372. Was McCrone the only consultant that Johnson 7 & Johnson asked to go beyond optical microscopy and 8 do something else to try to evaluate whether 9 Dr. Lewin was correct?</p> <p>10 A. No. They had additional people look 11 at it.</p> <p>12 Q. Who else looked at it that way?</p> <p>13 A. We covered this, but Dr. Fred Pooley.</p> <p>14 Q. And what did he conclude about 15 whether Dr. Lewin's findings were correct?</p> <p>16 A. In the conclusions to be drawn from 17 the examination are that no detectable chrysotile or 18 amphibole asbestos is present in the Shower to 19 Shower talc sample.</p> <p>20 Q. And another document you were asked 21 about, 'cause we've talked about a number of people 22 who were consultants to Johnson & Johnson, but 23 another document that the plaintiffs asked you 24 about, I guess it's Plaintiffs' Exhibit 1297. And 25 they asked you about this part about why Dr. Lewin</p>

<p style="text-align: right;">Page 158</p> <p>1 was selected to do this initial work, right?</p> <p>2 A. That's correct.</p> <p>3 Q. Now, this document actually also</p> <p>4 discusses some other labs that looked at Dr. Lewin's</p> <p>5 findings and evaluated whether they were correct, so</p> <p>6 I want to point that out.</p> <p>7 This is Dr. Schaffner writing. It</p> <p>8 says, "I've compared Dr. Lewin's results for</p> <p>9 chrysotile with those obtained for some of the same</p> <p>10 samples by four other laboratories. The additional</p> <p>11 two laboratories included in this part of the study</p> <p>12 are Columbia Scientific Industries of Austin, Texas</p> <p>13 who sell the stone apparatus for differential</p> <p>14 thermal analysis, and the health protection branch</p> <p>15 of the Department of National Health and Welfare of</p> <p>16 the Canadian Government in Ottawa.</p> <p>17 "The agreement of results from</p> <p>18 different laboratories is much less satisfactory for</p> <p>19 chrysotile than discussed above for tremolite. For</p> <p>20 example, Samples 89 and 173 were found by Dr. Lewin</p> <p>21 to contain five and 10 percent of chrysotile,</p> <p>22 respectively, but chrysotile was not found in these</p> <p>23 samples by the other laboratories."</p> <p>24 Do you see that?</p> <p>25 A. Yeah. It was 163, but yes, I see</p>	<p style="text-align: right;">Page 160</p> <p>1 with the plaintiffs' counsel about Dr. Langer. And</p> <p>2 to put this in -- I do have the full copy. I'll</p> <p>3 give you a copy.</p> <p>4 So now that we have a copy, I will go</p> <p>5 ahead and show the --</p> <p>6 MR. PANATIER: Your Honor, I make a</p> <p>7 scope objection.</p> <p>8 THE COURT: Sidebar. Bring that up.</p> <p>9 MR. PANATIER: I got it.</p> <p>10 (Sidebar.)</p> <p>11 MR. DUBIN: Your Honor, he brought up</p> <p>12 Dr. Lewin and discussed all Dr. Lewin and whether</p> <p>13 the findings were right, whether there were proper</p> <p>14 procedures used in order to verify or not verify</p> <p>15 Dr. Lewin's results. And I'm simply asking about</p> <p>16 this document that's in evidence about Dr. Lewin</p> <p>17 saying that he himself wouldn't stand behind his</p> <p>18 results.</p> <p>19 MR. PANATIER: It's outside the</p> <p>20 scope. I didn't do this. I discussed all of their</p> <p>21 testing. And, in fact, I went directly at what</p> <p>22 counsel did yesterday. I didn't bring up newspaper</p> <p>23 articles or anything.</p> <p>24 THE COURT: I must be confused. You</p> <p>25 brought up newspaper articles with regard to --</p>
<p style="text-align: right;">Page 159</p> <p>1 that.</p> <p>2 Q. 163.</p> <p>3 So were there other outside labs that</p> <p>4 were not consultants to Johnson & Johnson that also</p> <p>5 disagreed with Dr. Lewin's findings?</p> <p>6 A. They were not able to replicate them</p> <p>7 at those percentages, yes.</p> <p>8 Q. Including the health branch, health</p> <p>9 protection branch of the Department of National</p> <p>10 Health and Welfare of the Canadian Government</p> <p>11 Ottawa, correct?</p> <p>12 A. That was one of these entities they</p> <p>13 list here.</p> <p>14 Q. We've looked at Defense 7058.</p> <p>15 What did even Dr. Lewin say about</p> <p>16 Dr. Lewin's results?</p> <p>17 A. I'm sorry?</p> <p>18 Q. What did Dr. Lewin say about his own</p> <p>19 results?</p> <p>20 A. I'm sorry. Is this -- can I see the</p> <p>21 whole thing here? I'm sorry. I'm not sure if this</p> <p>22 is --</p> <p>23 Q. Well, if you can't read it enough,</p> <p>24 I'll skip it. It's already in evidence.</p> <p>25 There was also a lot of discussion</p>	<p style="text-align: right;">Page 161</p> <p>1 MR. PANATIER: Langer.</p> <p>2 THE COURT: -- Langer years later.</p> <p>3 This is permissible. I mean, it's</p> <p>4 within the scope. It just uses a document that you</p> <p>5 didn't use.</p> <p>6 MR. PANATIER: All right.</p> <p>7 THE COURT: It's on that issue.</p> <p>8 Go ahead.</p> <p>9 (Sidebar ends.)</p> <p>10 BY MR. DUBIN:</p> <p>11 Q. So we were just finishing off</p> <p>12 Dr. Lewin.</p> <p>13 THE COURT: Can you just give a</p> <p>14 marking to that?</p> <p>15 MR. DUBIN: This is Defense Exhibit</p> <p>16 7058. This is just a full copy of it.</p> <p>17 THE COURT: Okay. I see. Thank you.</p> <p>18 MR. DUBIN: The full copy is in</p> <p>19 evidence.</p> <p>20 BY MR. DUBIN:</p> <p>21 Q. Even Dr. Lewin himself, what did he</p> <p>22 say about his results?</p> <p>23 A. He says in the article referred to,</p> <p>24 "I was erroneously quoted as having reported that</p> <p>25 Johnson & Johnson's talcum powder contained two to</p>

1 three percent asbestos. In actual fact, I reported 2 that of 11 samples of the products of this company, 3 I found no evidence of asbestos in nine of the 4 samples and the other two samples fell into the 5 inconclusive category described above." 6 Q. And so you were also asked a lot 7 about Dr. Langer, and you were shown a comment that 8 he made in a newspaper article very recently. 9 But to start out with Dr. Langer, we 10 did see an earlier newspaper article before, Defense 11 7032, that dates from the actual time around which 12 he's doing his work. And what did even Dr. Langer 13 say about Dr. Langer's work? 14 A. Well, I'm just going to read this. 15 "The data were very preliminary in 16 nature and what is more, I may have mistaken long 17 talcum fibers for asbestos fibers. They have 18 similar properties, the doctor said." 19 Q. And we looked at another article 20 previously. This was back again at the time, 21 Defense Exhibit 8402. And what are they reporting 22 back then about what Dr. Langer and Mount Sinai had 23 found with regard to Johnson's Baby Powder and 24 medicated powder? 25 A. It states, "The products that the	Page 164 1 institution, not for our research group. He 2 reiterated that his team had detected asbestos in 3 Johnson's Baby Powder. I stand by that today. 4 Absolutely." 5 Right? You were shown that? 6 A. I was. 7 Q. I want to talk about what that 8 Dr. Chalmers thing is and what happened. 9 MR. PANATIER: Your Honor, we have to 10 approach on scope. 11 THE COURT: Sure. 12 (Sidebar.) 13 MR. PLACITELLA: It may be 14 unintentional, but every time Mr. Panatier makes an 15 objection counsel should not be throwing his hands 16 in front of the jury. 17 MR. DUBIN: You're right. I 18 apologize. 19 THE COURT: You won't do that again. 20 MR. DUBIN: I won't. 21 THE COURT: After we finish Langer, 22 we'll take the lunch break. 23 Your -- 24 MR. PANATIER: My objection is that 25 this is outside the scope. What they're going to do
Page 163 1 researchers found uncontaminated with asbestos 2 fibers were Ammens Medicated Powder; Avon Bird of 3 Paradise Beauty Dust; Diaperene Medicated Body 4 Powder; two Johnson's Baby Powders, one made here 5 and one in Britain; Johnson's Medicated Powder; 6 Mennen Bath Talc; Yardley Aftershave Powder and 7 Yardley Original Body Powder." 8 Q. And again, rather than things in the 9 newspaper, before we also looked at an actual 10 published paper, Defense Exhibit 8096, where 11 Dr. Langer and his colleagues at Mount Sinai 12 published a paper about various talcum powder 13 products that they looked for the presence of 14 asbestos, right? 15 A. That's correct. 16 Q. Did they report any asbestos in any 17 of the Johnson & Johnson products? 18 A. They did not. 19 Q. So then you were shown this comment 20 from December of 2018, and that's many decades after 21 the actual work was done? 22 A. This would be. Yes. 23 Q. And the comment you were shown is "In 24 recent interview, Dr. Langer told The Times that 25 Dr. Chalmers spoke for himself and not for the	Page 165 1 is they're now getting into, is that the press 2 release? 3 THE COURT: Right, Chalmers. 4 MR. PANATIER: Right. 5 So the fact that he said that in 6 order to, in order to read the full sentence, which 7 it's one full sentence to talk about how Langer 8 stands by his results, I had to read the full 9 sentence. 10 But we didn't talk about the Chalmers 11 press release. We didn't get into it at all. 12 THE COURT: It doesn't matter. You 13 raised the issue. And what you read to the jury was 14 Chalmers spoke for himself. 15 So by, going beyond the scope would 16 be like a totally separate issue. This is the 17 issue. 18 MR. PANATIER: It's -- okay. That's 19 fine. 20 THE COURT: That's my ruling. 21 MR. PANATIER: I'll come back with 22 the meeting where they met with her, that's fine. 23 THE COURT: You'll approach me first 24 before you do that. 25 (Sidebar ends.)

<p style="text-align: right;">Page 166</p> <p>1 BY MR. DUBIN:</p> <p>2 Q. So the reference to Dr. Chalmers, I 3 want to make sure we understood what that was. This 4 is Defense Exhibit 7506.</p> <p>5 A. Do you have the full --</p> <p>6 Q. (Handing.)</p> <p>7 So, this was from the archives of 8 Mount Sinai, the Office of the President and Dean, 9 Thomas C. Chalmers, from back in 1976. And it's 10 regarding "Recent media reports concerning research 11 on talcum powder carried out by the Mount Sinai 12 Medical Center created considerable confusion on the 13 part of the public.</p> <p>14 "The Medical Center has issued the 15 following statement in order to correct any 16 misinterpretations or mis-impressions that media 17 reports may have given."</p> <p>18 And then one of the things they go on 19 to talk about --</p> <p>20 A. I'm sorry, you're on page 3 of 7?</p> <p>21 Q. I'm now going to page 2.</p> <p>22 A. Page 2. Okay.</p> <p>23 Q. Two of the things that they said, 24 Dr. -- or Dr. Langer's institution, The Mount Sinai, 25 it says, "Although the news media specifically</p>	<p style="text-align: right;">Page 168</p> <p>1 A. I do.</p> <p>2 Q. And Dr. Chalmers writes, "I do feel 3 that we should not be afraid to admit it when we 4 have made a mistake."</p> <p>5 Do you see that?</p> <p>6 A. Yes, I do.</p> <p>7 Q. And that was Dr. Langer's 8 institution?</p> <p>9 A. This is from Dr. Thomas Chalmers to 10 Dr. Irving Selikoff, both at Mount Sinai at this 11 time, I believe.</p> <p>12 MR. DUBIN: Okay. I think it's time 13 for a lunch break.</p> <p>14 THE COURT: Members of the jury, 15 we're going to take the lunch break now. Leave your 16 notebooks here.</p> <p>17 Remember the instructions I've 18 provided: No discussions with regard to this case, 19 including the testimony you've just heard. No 20 research of any kind whatsoever.</p> <p>21 Please be ready to come back upstairs 22 at 1:25. Thank you. Enjoy your lunch. Wear your 23 juror badges where they are visible. Thank you.</p> <p>24 (Jury exits.)</p> <p>25 THE COURT: We're off the record.</p>
<p style="text-align: right;">Page 167</p> <p>1 emphasized the dangers of talcum powders advertised 2 for babies, the only baby powder tested that was 3 reported to show asbestos represents less than one 4 percent of the market and that sample was five years 5 old. The most commonly used baby talc has been 6 consistently free of asbestos."</p> <p>7 Do you see that?</p> <p>8 A. I do.</p> <p>9 Q. And do you understand that to be 10 Johnson & Johnson?</p> <p>11 A. I would -- I would make that 12 assumption, yes.</p> <p>13 Q. And the other thing that Mount Sinai 14 wrote back in 1976 is, "It is the opinion of Mount 15 Sinai's Department of Pediatrics that baby talc is a 16 useful and safe product."</p> <p>17 Do you see that?</p> <p>18 A. I do.</p> <p>19 Q. And then what we see on the next page 20 in terms of why this was done, there's a memo --</p> <p>21 A. I'm sorry. You're now on page 4 --</p> <p>22 Q. I'm now on page 4 of 7.</p> <p>23 There's a memo between a Dr. Irving 24 Selikoff and Dr. Thomas Chalmers.</p> <p>25 You see that?</p>	<p style="text-align: right;">Page 169</p> <p>1 (Luncheon recess taken from 2 12:22 p.m. to 1:28 p.m.)</p> <p>3 A F T E R N O O N S E S S I O N</p> <p>4 COURT OFFICER: Jury's entering.</p> <p>5 (Jury enters.)</p> <p>6 THE COURT: Please be seated. Make 7 sure cell phones are turned off</p> <p>8 Mr. Dubin, whenever you're ready</p> <p>9 Do you want us to go off the record?</p> <p>10 MR. DUBIN: No. We're fine.</p> <p>11 BY MR. DUBIN:</p> <p>12 Q. Hi, Dr. Sanchez. How are you?</p> <p>13 A. I'm well.</p> <p>14 Q. So we left off talking about some of 15 these boards, and again, I'm not going to go through 16 all the ones that we went through yesterday, that 17 plaintiffs' counsel didn't ask you, but again, there 18 were a number of these entries where they say 19 something like tremolite or amphibole, were those 20 asbestos; in other words, things like the Battelle 21 documents?</p> <p>22 A. No, you have to look at the specific 23 documents and what do they mean.</p> <p>24 Q. So let's then move on.</p> <p>25 I want to talk about some of the new</p>

1 documents that were shown to you today by the 2 plaintiffs' counsel. And I'm going to start here. 3 This was marked as Plaintiffs' Exhibit 3695-247. 4 And to make sure we know what we're looking at here, 5 there's a stamp on the bottom that says, "Imerys." 6 And I don't think it's disputed, but that this is 7 not a Johnson & Johnson document or a document from 8 Johnson & Johnson's files, just to put that in 9 context. 10 Do you see here one of the things 11 they've noted is that this company, Imerys, has 12 printed out some data regarding some old test 13 results where, in something called Grade 96 14 composite, they've identified, in a couple tests, 15 one chrysotile structure in those tests; right? 16 A. Correct. 17 Q. So I want to talk a little bit about 18 the significance of finding or not finding one 19 chrysotile structure in a test like this. 20 And we have sort of alluded to this 21 yesterday when we talked about these standards about 22 detection limits. Can you just describe again to 23 the jury what a detection limit is and how it's 24 used? 25 A. I'll try. It's somewhat of a	Page 170 1 methods used throughout the study of asbestos, 2 including Government regulations and standards? 3 A. It is. 4 Q. Okay. And, in fact, we looked at 5 this document, it cites to an ASTM standard. Do you 6 see that, ASTM D? 7 A. I do. 8 Q. And first of all, what's the ASTM 9 again, if you can remind the jury? 10 A. It's the American Standard and 11 Testing -- and Materials, or I forget what it is 12 exactly, something like that. 13 Q. And has the ASTM written about the 14 purposes and significance of these kind of detection 15 limits? 16 A. They do. They have a method 17 specifically for the determination of detection 18 limit based on counts. 19 Q. I want to look at that and see what 20 the actual method says based on the significance of 21 finding something like one chrysotile fiber. And 22 I'm going to use this. 23 And I'm not going to introduce it, 24 but do you want us to still assign a number to it? 25 THE COURT: Still assign a number to
Page 171 1 difficult concept. I appreciate that. 2 When you're doing particle counts 3 such as this bench sheet represents, the idea here 4 is if you go through and you analyze and you don't 5 see anything, meaning you have a zero count, there's 6 a 95 probability if you go and analyze again you 7 could see anywhere from nothing again up to three. 8 If you go in and you do an analysis 9 and you see one particle, there's a 95 percent 10 probability that you go back in and you will see no 11 particles, or you could see one particle or two 12 particles. 13 So as you go through and you look at 14 the probability on the counts, up until you get to 15 about three, assuming your background is completely 16 clean, a count of one, if you are trying to 17 reproduce that, you have a likelihood of getting 18 nothing detected on your second round. 19 So because of that, it's in what I 20 call the noise of the analysis. It's in the 21 uncertainty of the measurement. So we use detection 22 limits to ensure that whatever is being observed is 23 above and can be distinguished from the zero count. 24 That's all these methods are protecting against. 25 Q. And is that a common concept in	Page 173 1 it. 2 MR. DUBIN: We'll call it S-7. 3 THE COURT: Thank you. 4 (S-7 was marked for identification.) 5 BY MR. DUBIN: 6 Q. Here we're looking at something by 7 the ASTM called Standard Practice For Asbestos 8 Detection Limit Based on Counts. Is this something 9 you're familiar with? 10 A. I am. 11 Q. So we have here discussion of this 12 idea of needing to find a certain amount of fibers 13 for a positive. And one of the first things it 14 discusses is just the general concept. And this is 15 not something written by Johnson & Johnson, right? 16 A. Correct. 17 Q. What it says is, "The detection limit 18 is one of a number of characteristics used to 19 describe the expected performance of a measurement 20 method. The DL concept addresses certain potential 21 measurement interpretation errors. Specifically, a 22 measurement is reported as being below the DL if the 23 measurement cannot be distinguished from zero or 24 from the randomly varying background contamination 25 level."

1 So can you describe what that part 2 means? What does it mean that it's reported as 3 below the DL if the measured level cannot be 4 distinguished from zero or from the randomly varying 5 background contamination level? 6 A. It's just what I described when you 7 were with those very low counts, it's within just 8 the analytical uncertainty of the measurement, you 9 could analyze the same talc over and over again and 10 never see anything again. So you can't establish 11 that count of one from the background of zero. 12 So again, it just has to do with the 13 counts. And again, it reflects the noise of the 14 analysis or the uncertainty of the measurement. 15 Q. And what it says right after that is 16 that "Stated differently, the DL provides protection 17 against a false positive finding." 18 What does that mean? 19 A. A false positive finding is where 20 asbestos is reported when it really is not there. 21 So that's one of the reasons why DLs are used is to 22 protect against the false positive finding. 23 Q. And these kind of findings that we 24 see from the, even internal to the supplier about 25 this one chrysotile structure here or there, how	Page 174	Page 176
1 does that relate to the concept of detection limit? 2 A. Well, within D-6620, which we were 3 just looking at, this is all within that noise of 4 the analysis, and so when they're reporting out 5 their concentrations it's less than whatever that DL 6 is for that method that they're employing. 7 Q. So are all of these under the levels 8 of detection limit that is intended to provide 9 protection against the false positive finding? 10 A. Yes. They would be. 11 Q. Okay. And then another document that 12 you looked at from the time period of Vermont was 13 again an Imerys document. That was Plaintiffs' 14 Exhibit 3695-248. Imerys, again this is an Imerys 15 document, not a Johnson & Johnson document, right? 16 A. Correct. 17 Q. Okay. And do you know whether 18 something like this would even have been shared with 19 Johnson & Johnson? 20 A. I have no knowledge to that. 21 Q. Okay. But irrespective, this is 22 somebody at the supplier at a company called Rio 23 Tinto Minerals discussing an analysis of a fibrous 24 material from Argonaut and it says, "A sample of 25 acicular mineral material collected at the Argonaut	Page 175	Page 177
1 mine was submitted for identification." 2 Do you see that? 3 A. I do. 4 Q. Is this, does this indicate anywhere 5 that this is an analysis of a production run or sold 6 talc or anything like that? 7 A. No. My recollection of other 8 documents, this is dealing with a material they were 9 looking at potentially using for road-based 10 material. 11 Q. So does this even have anything to do 12 with talc used in baby powder? 13 A. No. This has nothing to do directly 14 with the production of a cosmetic grade talc in that 15 deposit. 16 Q. And one of the interesting things I 17 think we see here, do you see the way that they 18 describe it. It says, "The sample was identified as 19 asbestiform actinolite amphibole." 20 You see that? 21 A. I do. 22 Q. Does that indicate to you what we 23 should -- now, you don't disagree that whatever 24 they're analyzing here is asbestos, right? 25 A. No. It looks like an amphibole type		Page 177

<p style="text-align: right;">Page 178</p> <p>1 identification you can use if you're going to put it 2 up there. I understand what you're saying in terms 3 of a Bates number, but you have to use the 4 identification number.</p> <p>5 MR. DUBIN: I understand, your Honor. 6 And again, we're working with plaintiffs' counsel in 7 getting this.</p> <p>8 MR. PANATIER: It's got a sticker on 9 it.</p> <p>10 THE COURT: I know.</p> <p>11 MR. DUBIN: Fine. It has a 12 plaintiffs' sticker on it, 3695-253. I believe we 13 understand this is a printout of some spreadsheet, 14 but anyway...</p> <p>15 BY MR. DUBIN:</p> <p>16 Q. It says, what it has here is it has, 17 again, a finding of one chrysotile fiber back in 18 January of 2003, and then they have something, I 19 guess one, January 2001.</p> <p>20 First of all, do you know whether 21 Johnson & Johnson was even using Chinese talc at 22 this time in 2001?</p> <p>23 A. My understanding, they were not.</p> <p>24 Q. Okay. So these kind of fibers, are 25 we talking about the same thing where you find one</p>	<p style="text-align: right;">Page 180</p> <p>1 A. Correct.</p> <p>2 Q. So finally, I want to get back to 3 this idea of whether the testing boards we discussed 4 were accurate. And you were asked about this 5 document, the Crosetto ore document.</p> <p>6 Do you recall that?</p> <p>7 A. I do.</p> <p>8 Q. It was talking about the 9 mineralization of the general valley, right?</p> <p>10 A. Correct.</p> <p>11 Q. Again, we covered this yesterday. Is 12 it different to say what kind of minerals are in a 13 valley versus what are found in a part of an area 14 like a mine that's being actually processed for 15 consumer talc?</p> <p>16 A. Yeah. I mean, what's being done here 17 is he's saying, if you look at the geology of the 18 whole valley, these are the things that we're 19 finding potentially there, and then here's some 20 samples from the talc mine itself, test those. So 21 we need to look at the test results of the material.</p> <p>22 Q. And in terms of the boards, you know, 23 whether they're accurate or not, is there a lot of 24 other testing that doesn't appear on the boards 25 about talc used by Johnson & Johnson?</p>
<p style="text-align: right;">Page 179</p> <p>1 stray chrysotile fiber in an analysis?</p> <p>2 A. Again, they're applying the 3 statistical uncertainty of the measurement for their 4 detection limits, so one would be below their 5 detection limit.</p> <p>6 Q. Okay. And presumably if the 7 supplier, and this is not -- if the supplier is 8 doing analysis back here 2001, 2003, do you have an 9 understanding of whether they continued to look at 10 these kind of talcs for a long time thereafter?</p> <p>11 A. I believe they -- yes. I have seen 12 other testing records in those other years from the 13 supplier.</p> <p>14 Q. So if plaintiffs are coming to you 15 with an indication of like one chrysotile fiber in 16 2001 and one in 2003, what does that suggest to you 17 about whether they're really finding chrysotile from 18 the ore in the product here?</p> <p>19 A. Again, this is just suggesting 20 whatever they're seeing, it's below the method's 21 ability to really say what was there. You're still 22 within that noise of the analysis.</p> <p>23 Q. And then we see a number of other 24 zeros and presumably others in different time 25 periods, right?</p>	<p style="text-align: right;">Page 181</p> <p>1 A. Yes.</p> <p>2 Q. And even in this specific instance 3 about Crosetto, it says one drum of Italian rock, 4 the actual -- was sent for analysis. And then we 5 looked yesterday at Defense 7026 and when that was 6 actually analyzed, what did the Colorado School of 7 Mines report?</p> <p>8 A. Again, it looks like they hand-picked 9 through the bucket of rocks and the materials and 10 they didn't find any amphibole serpentine phases; 11 recognizes they were picking through it, and then 12 also when they were running the powdered samples 13 through the X-ray diffractometer they were also not 14 detecting any amphibole or serpentine phases.</p> <p>15 Q. And you were also asked by 16 plaintiffs' counsel about this, again, about this 17 Paoletti article, right?</p> <p>18 A. Yes.</p> <p>19 Q. And just to point out, first of all, 20 they were talking here about and analyzing talcs 21 used in that market, including various different 22 industrial and cosmetic talcs, right?</p> <p>23 A. Correct.</p> <p>24 Q. And does it still, do you still have 25 an opinion, sitting here today, whether anywhere in</p>

Page 182 1 here they say they found asbestos in the talc that 2 Johnson & Johnson was using -- is there more than 3 one Italian talc? 4 A. It's not even saying that. It's 5 saying they're purchasing talcum powders from the 6 Italian market. You don't know the source of any of 7 those products. They could be from Italy, they 8 could be from other sources. All we know is they 9 were purchased in Italy. We don't know anything 10 about the provenance of the talcs being tested. 11 Q. Again, is there anything on this 12 study that's on the board that said they tested 13 Johnson & Johnson talc and found asbestos in it? 14 A. There's nothing in the document that 15 says that. 16 Q. And, you know, as we walk through 17 things in the boards, if you see, you know, an 18 individual questioned issue in a particular document 19 or another document, is it important to consider the 20 evidence as a whole in terms of interpreting them 21 and understanding them? 22 A. As much as you can, yes. 23 Q. Okay. And so, we talked about things 24 like the board having Dr. Pooley's Italian on there. 25 That was 7044. But we also know that, you know,	Page 184 1 consider the totality of the evidence, as counsel 2 just said, it opens the door to the totality of the 3 evidence. 4 MR. DUBIN: I'll withdraw my 5 question, that's fine. I'll move on from Pooley. 6 There's some (inaudible). 7 THE COURT: Thank you. 8 (Sidebar ends.) 9 BY MR. DUBIN: 10 Q. Okay. I won't belabor the point. 11 We did look at a number of other 12 documents that are not listed on here about people's 13 evaluation of Johnson & Johnson talc, right? 14 A. We did. 15 Q. And did that include some of the 16 preeminent experts in the fields of microscopy and 17 asbestos analysis? 18 A. At that time, yes. 19 Q. And as a final issue, I just want to 20 ask you a few things. 21 One of the things that you were asked 22 about was the amount of material that you can test 23 by TEM and whether it's a breath mint or something 24 else. First, I know you seem like you were trying 25 to clarify something about weight, but I'm not sure
Page 183 1 when we saw, for example, something about Grade 66 2 or 96, which was Vermont, we looked at another 3 document which was from Dr. Pooley about 7046; did 4 he also do an analysis of the Vermont talc? 5 A. He did. 6 MR. PANATIER: Scope. 7 THE COURT: Sidebar. 8 (Sidebar.) 9 THE COURT: How is Pooley and Vermont 10 raised on cross-examination? 11 MR. DUBIN: They're showing 12 individual Grade 66 or 96 where he was crossed on 13 finding. As Dr. Sanchez pointed out, understand 14 things like that, whether they're really positive 15 findings, also have to look at other evidence, the 16 totality of the evidence and briefly pointing out 17 what some of that totality of the evidence is. 18 THE COURT: Okay. 19 MR. DUBIN: To put it in context. 20 I've only got a few slides left. 21 THE COURT: Thank you. 22 You wish to be heard on that? 23 MR. PANATIER: Sure. 24 I didn't get into Vermont stuff at 25 all. And to try to gateway it by saying we have to	Page 185 1 what that was. 2 A. Well, if you're calculating out a 3 structures per gram, which is what we're dealing 4 with, you're always dealing with a mass. So I was 5 just trying to clarify that when the conversation 6 was being confused of only particles by particles. 7 Q. Okay. And when we talk about the 8 idea that you can only look at a small amount of 9 material by weight in TEM, what does that have to do 10 with? 11 A. It's limitations of that technique. 12 It's by nature of how high a magnification it is, 13 you only ever can look at very small amounts of 14 material and only very small particles just by 15 nature of what it is. 16 Q. But when you're looking at that small 17 amount of material, can you get down still to a 18 very, very low level of sensitivity in terms of 19 being able to detect something? 20 A. Yes. 21 Q. Like approximately how low are we 22 talking about here? 23 A. Again, it depends on the analysis. 24 You have to look at the amount of material, how it 25 was prepared in order to arrive at it, but you're

1 generally in the parts per million or parts per 2 billion range. 3 Q. And because of that limitation of 4 TEM, what do you then do when you're evaluating talc 5 in order to try to look at a larger amount of 6 material? 7 A. Well, this goes back to the approach 8 of looking at the material in the mine itself, using 9 powder X-ray diffraction is looking at two grams of 10 material per test. And all these things that you're 11 sampling, again, you're trying to sample these 12 things in a way that's representative of larger 13 material and you extrapolate out to the larger 14 material. 15 But, again, you use X-ray 16 diffraction, you use polarized light microscopy and 17 you use TEM. You use those things all in 18 conjunction. 19 Q. I guess you're making a good point. 20 Let's just focus on the microscope 21 part first, or machine. Are there other types of 22 analysis besides the transmission electron 23 microscope that Johnson & Johnson has used that will 24 allow you to look at a larger amount of material? 25 A. Yes.	Page 186	1 A. Thousands of pages of documents, 2 looking into the older techniques of the time. 3 Again, when I'm reading the documents, where I can, 4 especially with the testing methodologies through 5 time as they have changed and again, some of the 6 uncertainty in the early '70s I was discussing, 7 actually looking at the documents for what they were 8 doing in their methodology, and then to evaluate, by 9 following that methodology, could you actually 10 arrive at a scientifically supportable conclusion 11 asbestos was present. 12 So again, you look into that, you 13 look at the properties they're measuring and take 14 that into account. 15 Q. And again, we're not going to talk 16 about the substance of it given where we are in the 17 trial, but again, can you give the jury a sense of 18 the volume of work that has been conducted by you or 19 at your direction at RJ Lee to look back at 20 historical samples of Johnson & Johnson products? 21 MR. PANATIER: Sidebar, your Honor. 22 THE COURT: Sidebar. 23 (Sidebar.) 24 MR. PANATIER: They're trying to get 25 the fact that he's done testing. And he kind of did	Page 188
1 Q. Which are those? 2 A. One of those would be polarizing 3 light microscopy. Another one is powder X-ray 4 diffraction. 5 Q. And then if you want to take a step 6 back and no longer be just looking at something 7 zoomed in under a microscope, are there other ways 8 that you can evaluate a mine or deposit or areas 9 within it to determine whether it's likely to have 10 asbestos? 11 A. Yes. If you can actually go and look 12 at the rock before it's turned into a powder you can 13 see whether there's veins of asbestos in the 14 material before it ever would be processed. You can 15 evaluate things of that nature in the field. 16 Q. Is that something Johnson & Johnson 17 also did? 18 A. That is. Yes, they did. 19 Q. And finally, you were asked a little 20 bit about money, and I just wanted to make it clear, 21 as part of the work you've done that your company 22 has been compensated for, you know, can you give the 23 jury a sense of the volume and number of documents 24 that you've reviewed to satisfy yourself about your 25 opinions?	Page 187	1 this already in -- first of all, this is outside the 2 scope. 3 Second of all, when they started 4 yesterday they kind of squeezed this in where he 5 said, oh, I tested Johnson & Johnson, I stand by my 6 results. This is another opportunity for him to say 7 that. I think that goes way too far. 8 MR. DUBIN: The one I asked him about 9 when he said he stands by his results was outside 10 litigation testing. He went through the exact 11 dollar numbers that he's been paid in all of these 12 cases where you know that what he was doing in part 13 was generating gigantic reports, doing analyses, 14 responding to Dr. Longo. How can I not at least 15 say, you know, we're not just giving him free money 16 and that he's actually worked for it like he's done 17 with the analysis. 18 MR. PANATIER: I think it's perfectly 19 fine to say have you been paid for testing. That's 20 it. We're talking about historical samples, say 21 that is, they're trying to get that in however they 22 can. And he did it yesterday. He actually was 23 asked about not just Johnson & Johnson samples, 24 about historical tests. And he said we stand by our 25 results. Ask him if he's done testing and if they	Page 189

1 got paid for it. 2 MR. DUBIN: Your Honor, again, I 3 think once you get into a dollar number, how can I 4 not ask how much work did you do for that? But I 5 leave it to your Honor. I'm not going to continue 6 to argue it. 7 THE COURT: How much work he's done 8 is fine. Do not ask any question to elicit the 9 results of his tests. 10 MR. DUBIN: I'm going to remind him 11 again, as I tried to do in the preface, and I'm 12 going to say -- 13 THE COURT: I think it's a little bit 14 better than yesterday, so thank you for chatting 15 with him, but let's wrap this up. 16 I agree it's important in terms of, 17 to counter the issue of payment, work that he has 18 done, but no results. 19 MR. DUBIN: Okay. I'll try to remind 20 him of that in preface in my question. 21 THE COURT: Yes. Thank you. 22 (Sidebar ends.) 23 BY MR. DUBIN: 24 Q. Where this trial is now we're not 25 talking about results. We're just, you know, just	Page 190 1 Q. And did many of those experts report 2 to Johnson & Johnson that there was no asbestos? 3 A. They did. 4 Q. And were there also Government 5 findings and investigations that had reported that 6 there was no asbestos in Johnson & Johnson's talc? 7 A. There were. 8 MR. DUBIN: Okay. Thank you very 9 much. 10 THE COURT: Sidebar with regard to 11 any proposed recross. Thank you. 12 (Sidebar.) 13 THE COURT: What are you seeking to 14 do by way of recross and how do you think it's 15 appropriate? 16 MR. PANATIER: Yes, your Honor. 17 The 2008 report from Argonaut, he 18 said that was for road material. That's incorrect. 19 THE COURT: Right. 20 MR. PANATIER: This one is. So I 21 need to straighten that out. 22 THE COURT: Okay. I'll allow that. 23 MR. PANATIER: The Chalmers, the 24 press release. 25 THE COURT: Yes.
Page 191 1 in terms of you were asked about the amount of money 2 that has been paid to the company, so I want to ask 3 about the volume of work that you've done, you know, 4 at RJ Lee, what the compensation for it is in terms 5 of analyzing how many historical samples and the 6 volume of reports and materials that have been 7 prepared. 8 A. Yeah. Not speaking of any results of 9 that testing, but again, we have tested over a 10 hundred samples directly tied to the litigation. We 11 have examined the documents. We have done many 12 hours of literature search trying to understand the 13 science of the time. 14 There's a lot of data that comes in 15 from plaintiffs' experts that we need to evaluate. 16 Every time there's a diffraction pattern we have to 17 go in there and make measurements and match those 18 measurements up to try to verify the findings. So 19 there has been a lot of work done. 20 Q. Okay. And so if we end where we 21 started, just to make clear, if we look at the 22 evidence that you discussed with us and with 23 plaintiffs' counsel, did Johnson & Johnson hire a 24 number of prominent experts to look at its talc? 25 A. They did.	Page 193 1 MR. PANATIER: So I have the Johnson 2 & Johnson memo about their meeting with Chalmers. 3 THE COURT: That's fine. 4 MR. PANATIER: And then lastly, he 5 brought up the detection -- 6 THE COURT: ASTM. 7 MR. PANATIER: ASTM. I'm just going 8 to ask a question about that in relation to this. 9 THE COURT: About the ASTM? 10 MR. PANATIER: Yes. 11 THE COURT: Okay. 12 MR. DUBIN: Your Honor -- 13 THE COURT: You get the final. 14 MR. DUBIN: No, it's fine. I'm 15 trying to explain the reason for confusion, I guess, 16 one of the documents seems to be a printout of part 17 of a spreadsheet, so I don't know whether we have 18 the -- he sent it to me now. We may seek to 19 introduce an additional part of that when he's off 20 the stand. I don't know, having not looked at the 21 whole thing. 22 MR. PANATIER: You have it as it was 23 produced to us by Imerys. 24 MR. DUBIN: I get it. I'll take a 25 look at that.

1 THE COURT: All right. Go ahead. 2 (Sidebar ends.) 3 THE COURT: Mr. Panatier, whenever 4 you're ready. 5 MR. PANATIER: Thank you, your Honor. 6 RECROSS-EXAMINATION BY MR. PANATIER: 7 Q. All right. Dr. Sanchez, just a few 8 things. 9 By way of example, we look at these 10 results, right; you talked about that for every lab 11 they have to determine and under that method, that 12 ASTM method, they have to determine what the 13 background is for that lab, correct? 14 A. That is correct. 15 Q. And do you know what the background 16 is for the lab that did this work? 17 A. Again, I believe that they have a 18 zero background level, which still encompasses 19 counts up to three. 20 Q. They have a zero background level, 21 right? 22 A. Based upon how you determine that, 23 yes. 24 THE COURT: For the record, that was 25 what document?	Page 194 1 Q. Well, this is Exhibit 3049. It's in 2 evidence. And we can, if we need to, we can count 3 the folks, 'cause it says here on March 22nd, 1976. 4 Now, the press release goes out the 5 next day, right? 6 A. I believe that's correct. 7 Q. Okay. A meeting was held with 8 Dr. Thomas Chalmers, and he's the one that issued 9 the press release, correct? 10 A. Correct. 11 Q. President of the Mount Sinai School 12 of Medicine. Dr. S.D. Pomrinse, that's an 13 interesting name, Pomrinse of the medical school and 14 Mr. Samuel Rovner, I got it, someone's trying to 15 tell me to highlight. 16 Let's see, Johnson & Johnson was 17 represented by Mr. D.D. Johnston, Mr. J.E. Burke, 18 D.D. Pettersen, Mr. L. Foster and Mr. Gavin 19 Hildick-Smith; one, two, three, four, five people, 20 right? 21 A. That's correct. 22 Q. Now, at the time, were you aware that 23 D.D. Johnston was the president of the Baby Products 24 Company? 25 A. I don't know what these people's
1 MR. PANATIER: 3695-247. 2 THE COURT: Thank you. 3 BY MR. PANATIER: 4 Q. They have objectively, when they 5 report chrysotile findings, someone is seeing the 6 actual asbestos in the sample, they are measuring it 7 and analyzing it, correct? 8 A. They saw something that they 9 identified as chrysotile, yes. 10 Q. That's right. 11 You're not saying that it's some 12 imaginary hypothesis, they actually saw the fiber? 13 A. Correct. That is why something is 14 counted. 15 Q. You were asked about -- you were 16 asked about a press release that Mount Sinai put out 17 on March 23rd, 1976. 18 Do you recall that? 19 A. I do. 20 Q. Now, sir, you know the day before 21 Mount Sinai issued that press release, five 22 employees were in the offices at Mount Sinai, 23 correct? 24 A. I don't know the number, but I 25 believe I have seen that document.	Page 195 1 positions are. 2 Q. We've got five people from Johnson & 3 Johnson showing up in the offices, right? 4 A. Correct. 5 Q. This is a Johnson & Johnson memo 6 about that meeting, correct? 7 A. Yes, I believe that's correct. 8 Q. The object of the meeting was to 9 review with the Mount Sinai school management the 10 need for a statement from them correcting the record 11 in the press to indicate that baby talc is safe, the 12 samples of talc assayed by the Selikoff group were 13 at least three years old and that nickel containing 14 talc was not a hazard. 15 Now, they put out an article, they 16 wrote a literature article that came out in 1976, 17 correct? 18 A. Who did? I'm sorry. 19 Q. Mount Sinai. 20 A. Some individuals from Mount Sinai. 21 Yes. 22 Q. Right. Okay. 23 So Johnson & Johnson is saying that 24 they need to issue a statement about that, correct? 25 A. I'm not sure what they're referring

<p style="text-align: right;">Page 198</p> <p>1 to here. It sounds like this is a press release 2 that they're looking into, not an article. 3 Q. Okay. All right. That's fine. 4 That's fine. 5 "Initially, Dr. Chalmers, who had 6 clearly given a lot of thought to the issue, 7 suggested that it might be wisest if all parties 8 forgot the whole incident and that nothing would be 9 gained by obtaining a retraction from the Mount 10 Sinai medical school. It was pointed out that a 11 follow-up story in the media and press would have 12 less impact than the initial story. 13 "Johnson & Johnson representatives, 14 however, clearly expressed their desire to have a 15 retraction statement not only to allay the fears of 16 many anxious parents, but to correct the record 17 concerning the safety of baby talc and the fact that 18 Mount Sinai scientists had failed to report that the 19 samples studied were at least three years old." 20 So they wanted a retraction and one 21 of the things they say is to allay the fears of 22 parents, right? 23 A. You read the document. That's what 24 it says. 25 Q. "The Mount Sinai group indicated that</p>	Page 200
<p style="text-align: right;">Page 199</p> <p>1 over the weekend the Selikoff group had been 2 studying six new samples of talc and had reported 3 that all of them contained minimal amounts of 4 asbestos. The Mount Sinai management thought that 5 this information should be in the retraction 6 statement, but the Johnson & Johnson group assured 7 the Mount Sinai management that such a statement 8 should be avoided in case it turns out that it was 9 wrong." Right?</p> <p>10 A. Yes.</p> <p>11 Q. So Mount Sinai, they show up in the 12 offices. Mount Sinai said we did some work over the 13 weekend, six more samples all contain asbestos. 14 Johnson & Johnson says no, you might be wrong, so 15 you shouldn't include those in the retraction, 16 right?</p> <p>17 A. I would agree that you shouldn't be 18 reporting findings if they're not verified.</p> <p>19 Q. Well, they didn't say they weren't 20 verified. Johnson & Johnson says you could be in 21 error, so you shouldn't include them. That's all we 22 know from this. Isn't that true?</p> <p>23 (Continuation of the day's 24 proceedings in Volume 2.) 25</p>	Page 200

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Exhibit 164

Date	Exhibit #	Testing Entity	Author	Recipients	Purpose Stated	Test method	Mine	What was tested	Special Preparation	What tests revealed	Hopkins Comments	Comments
10/15/1957 J&J-309		Battelle	Smith					Italian talc processed talc: Italian		"the Italian talc averages about 10% fibrous or angular particles"		
5/9/1968 J&J-1		Battelle	Smith	Dr. Lycan		petrograph	Val Chisone	1		tremolite tremolite;		
5/29/1958 J&J-2		Battelle	Smith	Dr. Lycan		microscope	Val Chisone	1		6 to 10 % fibrous talc		
12/4/1970 J&J-9		Colorado School of Mines	Colorado School of Mines	Miller	XRD & petrograph	Hammondsville	38 core samples			tremolite-actinolite; fibrous talc		
3/9/1971 J&J-257		McCrone	Grieger	Goudie		SAED; XRD		Shower to Shower; medicated powder		"fiber of chrysotile... Was very clear"; "medicated powder we found one fiber of chrysotile". Shower to Shower...we feel strongly that it may be chrysotile... chrysotile is very low", >>> Final Report >>"Shower to Shower The fiber content of Shower to Shower is quite low in comparison to previous samples which we have investigated... We found three suspect fibers . Of these, two were found in one field and probably have the same source, very possibly contamination... It is still questionable whether they are chrysotile. We have, however, found traces of chrysotile in G-11 one of the additives to Shower to Shower , and this might be a possible source of these contaminant fibers."		EXHIBIT Hopkins-28 Date: 11-5-78 MLG, CSR, RPA, CRR
5/14/1971 J&J-255	J&J	Ashton	Smith		XRD		Baby Powder (production batch)			tremolite; tremolite-actinolite		
7/2/1971 J&J-256		Colorado School of Mines	Pattengill	Ashton	XRD; PLM		six monthly plant run samples			5 of 6 show tremolite-actinolite, "no other forms of nontalc minerals approaching asbestos types were identified"		
7/7/1971 J&J-15		Colorado School of Mines	Pattengill	Ashton	XRD	Vermont talc	processed talc-344-L			tremolite & actinolite		
7/29/1971 J&J-19		Colorado School of Mines, McCrone, Dartmouth	Nashed	Foster	appearance and fiber content	electron diffraction	Vermont talc			"trace amounts of fibrous minerals; (tremolite/actinolite)"		
10/12/1971 J&J-23		McCrone	Grieger	Goudie				Shower to Shower		traces of chrysotile in one of additives		YES
11/11/1971 J&J-376		McCrone	Grieger	Goudie		TEM		Shower to Shower		"The Shower to Shower appeared to have a few more fibers than the other two samples ,however I think that might be due to possible contamination from the G-11. In the G-11 we did find two positively identified chrysotile fibers and some other fibers which at first glance appeared to be chrysotile, when you look at the electron diffraction pattern. I believe that most of the fibers in Shower to Shower which are suspect may come from G-11... I left out the comments on G-11 from the report because I felt you might want to change your supplier or investigate your supplier , and this would only tend to confuse the issue perhaps with the FDA."		EXHIBIT J&J-414

8/3/1972 J&J-28	NYU	Seymour Lewin	Dr. Weissler (FDA)	XRD	Shower to Shower sample 84	5%	YES
8/10/1972 J&J-373	J&J			PLM	Shower to Shower	"About 1 fiber or rod/needle every 500 particles. Approx 1/3 of these are tremolite."	
8/24/1972 J&J-29	Sperry Rand	Nashed	Dr. R. A. Fuller	SEM	Shower to Shower	"asbestos fibers could be detected in the sample", "reported chrysotile"	YES
8/31/1972 J&J-348	Sperry Rand	J.J. Wehrung		SEM	Shower to Shower	Dr. Weissler used SEM "to study general shape of chrysotile asbestos." "Dr. Weissler he did find fibers which had the general shape of chrysotile" Also found "asbestos form fibers" in samples brought by J.J. which were photographed."	
9/8/1972 D-7	Sperry Rand	J.J. Wehrung		SEM	Shower to Shower	Observation of asbestosform "more correctly be called fiberiform" SEM "very able to identify fiberforms which may be chrysotile"	
9/25/1972 J&J-31	Dr. Lewin	Dr. Nashed	Dr. Fuller	J&J Medicated Powder; Johnson's Baby Powder; J&J Shower to Shower	J&J Medicated Powder; Johnson's Baby Powder; J&J Shower to Shower	Meditated Powder tremolite 4% Baby Powder 2-3% chrysotile Shower to Shower 2.5% chrysotile	YES
10/27/1972 J&J-36,34,37	McCrone	Stewart	Goudie	XRD; TEM		"Both samples contained an insignificant amount of tremolite," tremolite rods	YES
2/25/1973 J&J-100	Colorado School of Mines	Reid	Ashton	XRD		tremolite-actinolite; slight trace of anthophyllite? Tremolite? "asbestos type materials"	YES?
4/26/1973 J&J-44	J&J	Pettersen	Johnston	PLM	Hammondsville Powder	"tremolite or actinolite are Indentifiable (optical microscope)and these might be classified as asbestos fiber"	NO
4/27/1973 J&J-375	J&J			optical microscope	Johnson's Baby Powder	trace amounts of amphiboles in all samples. "The optical properties of the spricles are closer to actinolite than tremolite"	
5/1/1973 J&J-367		Miller	Petterson		Hammondsville ore	"the ore body contains tremolite"	
5/8/1973 J&J-368	J&J				Hammondsville ore	"Your question this morning was how did Lewin assay timing relate to actinolite showings. Baby Powder lots 1087 & 1091 were alleged to contain asbestosform by Lewin. Talc shipments checked by microscope have showed all lots clean just prior to and right after that time. the first showing of actinolite we know about is October 1972. The implications are that things were in good shape when Lewin picked up the above two lots for his assays."	
6/6/1973 J&J-47	Cardiff	Pooley	Ashton	our Vermont talc	concentration technique	actinolite	
9/5/1973 J&J-258	FDA	Stuart		Shower to Shower sample 84		"fibers of tremolite/actinolite"	YES
12/21/1973 J&J-263	Colorado School of Mines	Reid	Ashton	Vermont talc samples centrifuge		"Identified chrysotile at a level of less than 10 ppm in the Vermont sample"	YES

4/25/1977 J&J-141	Gardiff	Pooley	XRD	Vermont composite sample	Fibers of actinolite composite samples large and small fibrous tremolite & actinolite	Source unknown- Mr. Bicks says look in Metadata	YES?
6/14/1977 J&J-246	EMV		SEM, XRD	ore & product			
2/9/1979 J&J-154	George Lee's Group	Cohen		66 composite samples			
9/1/1983 J&J-175	McCrone	Palenik	Miller	Argonaut, Rainbow	Argonaut - 118 fibers, Rainbow- 2650 fibers	Type of fiber not specified	YES
11/2/1984 J&J-179	McGrone	Palenik	Miller	NIOSH method	"airborne fiber concentrations"	5,500 to 60,000 chrysotile asbestos fibers All samples found asbestos	YES
5/15/1985 J&J-177	MSHA	Olson		TEM- EPA method	"analysis for asbestos"		
8/5/1985 J&J-184	McGrone	Laubenthal	Miller	PLM, XRD	analysis for "asbestiform minerals"	71.2% fibrous talc & "5.8% anthophyllite, an asbestosiform amphibole"	YES
3/30/1987 J&J-185	J&J	Schmidt	Miller	PLM	Hammondsville air samples	fibers in both samples	
4/15/1988 J&J-190	Skyline Laboratories, Aquatic Environmental			XRD		"Tremolite is present in the fines (minus 100 plus 200 mesh) in six volume percent as free needles"	
2/25/1992 J&J-202	Cyprus	Munro		Raymond Mill	Processed talc		
0/00/0000 J&J-298	McCrone				random and composite process samples		
02/09/1979 J&J-341	J&J	Lee		XRD	actinolite		
05/09/1988 J&J-311	Battelle	Smith	J&J				
1/12/1984 J&J-305	McCrone	Palenik	Miller	PLM	Talc powder, grade EV	Talcan talc	Johnson's Baby Powder
1/24/1985 J&J-310	Battelle	Brown	Lyon, J&J				
4/19/1973 J&J-296	J&J	Hamer					Dispersion staining

10/21/1973	J&J-335	Colorado School of Mines	J&J	Petrographic optical microscope	"trace amounts of amphibole" in all 4 samples tested; "Shape- prismatic, columnar, parallel-sided rods" Size: from 20X4 microns to 200X50 microns.; Identity : the optical properties of the minerals are closer to actinolite than tremolite"	Johnson's Baby Powder	Johnson's Baby Powder	
10/5/1976	J&J-303		J&J	optical microscope	"small (1%) amounts of amphibole needles."			
10/9/1972	J&J-342		J&J		"trace tremolite" In 1970 and 1971 samples		No chrysotile observed	
10/27/1973	J&J-299	Dutch consumer organization	J&J	electron microscope (REM)	" asbestos - content of 1.59%"	Johnson's Baby Powder	Plate 4682 A-HC 51,000X Chrysotile fiber	
10/11/1975	J&J-297	McCrone	J&J	petrograph	2 percent non platy talc in upper core; 14% (granular and fibrous) non platy talc with 1-2% altered amphiboles in lower core	Hammondsville core	"chrysotile asbestos does exist in the specimens of shower to shower"	
9/18/1961	J&J-333	Battelle	J&J	Ashton	claimed to have found asbestos	Johnson's Baby Powder	"Argonaut main ore body open pit ... high incidence of fibre bearing zones encountered in the main ore body"	
??/??/1972	J&J-33	Dutch Consumers	J&J	TEM	determine possible content of fibrous chrysotile asbestos		"areas with fibrous actinolite"	
10/20/1991	J&J-327	Cypress	J&J	Munro	Argonaut mine	Johnson's Baby Powder	chrysotile asbestos	Johnson's Baby Powder batch # 108T & 109T (Lewin Samples)
10/20/1991	J&J-327	Cypress	J&J	Munro	Hamm mine,			
7/9/??	J&J-17	Mt. Sinai	J&J	electron microscopy				
10/21/1972	J&J-27	University of Minnesota	J&J					Nashed Goudie

Exhibit 165

TRM WTH
B-
WCW FRI
GL

The Cosmetic, Toiletry and Fragrance Association, Inc.

1133 15th STREET, N.W., WASHINGTON, D.C. 20005 • 202/331-1770 • TELEX 89-2673

James H. Merritt
President

Norman F. Estrin, Ph.D.
Vice President—Science

March 15th, 1976

Mr. Heinz J. Eiermann
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

On March 11th, 1976, Mr. Eiermann --

-- the CTFA Talc Subcommittee met to discuss the current status of talc. It was recognized that a need exists to bring to your attention a profile of the analyses for asbestos form materials in talc used in the U.S. production of cosmetics and toiletry products.

The attached letters demonstrate responsibility of industry in monitoring its talcs. We are certain that the summary will give you assurance as to the freedom from contamination by asbestos form materials of cosmetic talc products.

Individual companies are more than willing to discuss the detailed data with you at your convenience.

Cordially,



Norman F. Estrin, Ph.D.
Vice President - Science

NFE:jj
Attachments

Exhibit 166

Johnson & Johnson

BABY PRODUCTS COMPANY

159902

Dr. N. F. Estrin
C.T.F.A.

-2-

March 15, 1976

NEW BRUNSWICK, N.J. 08903

March 15, 1976

Dr. Norman F. Estrin
Vice President - Science
Cosmetic, Toiletries, and
Fragrance Association
1133 15th Street, N.W.
Washington, D.C. 20005

Re: Examination for Asbestos In Talc

Dear Dr. Estrin:

The talc which is used by Johnson & Johnson is solely derived from its own mine in Vermont, where the ore is mined selectively and then beneficiated by the process of flotation.

Shipments of this highly purified talc are routinely examined by our own laboratory to verify the absence of asbestos minerals.

Historically, Johnson & Johnson has always been concerned about the mineralogical integrity of its talcs and even its earliest specifications have required the examination for acicular particulates. When it was erroneously reported in 1971 that our powder contained asbestos, we sponsored a scientific seminar of mineralogical and analytical experts for the FDA to prove that our talc is not contaminated with asbestos. At that time numerous samples were analyzed by experienced consultants such as McCrone Associates, Colorado School of Mines, Professor F. D. Pooley (of the University College, Cardiff), Professor G. Brown (of Princeton), and Professor M. Buerger (of M.I.T.). These examinations included X-ray diffraction analysis, differential thermal analysis, and transmission electron microscopy.

During the period December 1972 to October 1973, 93 lots were individually sampled and examined by X-ray diffractometry for the presence of asbestos minerals. No amphiboles or serpentine minerals were detected in any sample.

Beginning in October 1973, differential thermal analysis was added to our specified requirement. Both, differential thermal analysis and X-ray diffractometry were instituted for the routine examination of sequential lots. A further 100 lots have since been examined, applying both methods to each sample. Again, no amphibole or serpentine minerals have been detected.

I would like to advise that we are continuing to employ differential thermal analysis and X-ray diffractometry in the examination of sequential lots for the detection of amphibole and serpentine minerals.

It should be pointed out that we also maintain a worldwide monitoring of talcs used by our Johnson & Johnson affiliates, employing these same techniques.

Finally, let me add that periodically, we also submit sub-samples for Transmission Electron Microscope examination and these have always verified the absence of asbestos minerals.

It is our understanding that you would wish to submit this information to the FDA. Please regard this letter as non-confidential.

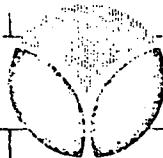
Sincerely yours,

George Lee
Director of Applied Research

GL/mm

WCD000009

Exhibit 167



The Cosmetic, Toiletry and Fragrance Association, Inc.

1133 15th STREET, N.W., WASHINGTON, D.C. 20005 • 202/331-1770 • TELEX 89-2673

J.H.M.
T.F.L.
P.M.
S.P.E.M.

James H. Merritt
President

Norman F. Estrin, Ph.D.
Vice President—Science

TALC SUBCOMMITTEE

M I N U T E S

A meeting of the Talc Subcommittee was held on March 31, 1976, at Bristol-Myers, 225 Long Avenue, Hillside, New Jersey. Those in attendance were:

George Sandland, Bristol-Myers (CHAIRMAN)
John Clements, Pfizer, Inc.
Christopher Costello, Colgate-Palmolive
John Facq, Colgate-Palmolive
Allan Harvey, R.T. Vanderbilt Co., Inc.
George Lee, Johnson & Johnson
Ray Krammes, Whittaker, Clark & Daniels
Roderick Mundy, Sterling Drug Inc.
Louis Murino, Cyprus Industrial Minerals
Fred Roesch, Whittaker, Clark & Daniels
Robert Rolle, Johnson & Johnson
Joseph Simko, Colgate-Palmolive
Terry Smith, Faberge
Harold Stanley, Charles Pfizer Co.
Ian Stewart, Walter C. McCrone Assoc., Inc.
Robert Suffis, Mennen Co.
John Travers, Avon Products, Inc.
Ronald Yakupcin, Kolmar Labs.
Norman Estrin, CTFA

Mr. Sandland opened the meeting and proceeded with the agenda.

1. Collaborative Study

Mr. Lee and Dr. Rolle updated the Subcommittee on reports of recent gathering of samples by the Mt. Sinai group. A suggestion was made that individual companies write directly to Mt. Sinai's management on the lack of creditability of Dr. Langer's results when applied to their specific products.

- 2 -

The advantages and disadvantages were discussed in detail of engaging in a collaborative study. It was generally felt the study could not be successful if there are restrictions on which talcs can be gathered. Many members favored engaging a collaborative study. Dr. Estrin suggested a proposal be put together to be presented to the CTFA Board of Directors (as was done in the case of the microbiological contents study several years ago). A subcommittee was organized to draw up this proposal consisting of Mr. Suffis, Mr. Lee and chaired by Mr. Sandland.

2. Periodic Reporting

The Subcommittee agreed on the success of the presentation of summary reports given to the FDA. Dr. Estrin suggested the Subcommittee should not obligate itself to give periodic reports to FDA but urged members to build their data base so that at some time in the future the Subcommittee can decide whether the time is right to present FDA with an update on industry analysis.

3. Review of Talc

The planned review of talc by the Miscellaneous OTC Drug Panel was noted. It was suggested CTFA begin at once to plan for a presentation to be made by a panel of experts, including independent experts, talc suppliers and manufacturers. The actual data for consideration by the Miscellaneous Panel of summary information on talc was not known.

5. Animal Studies

Dr. Estrin suggested consideration be given to planning animal studies on talc which may not be covered adequately by previous studies. Dr. Travers, Mr. Roesch and Mr. Lee will coordinate activities involving Dr. Gressel and Dr. Finkelstein to investigate this possibility.

6. Sampling

The Subcommittee agreed CTFA should not address the issue raised by Mr. Eiermann and Dr. Schaffner further with the FDA.

There being no further business, the meeting adjourned.


Norman F. Estrin, Ph.D.
Vice President - Science

NFE:mp

Exhibit 168

George Lee

Johnson & Johnson

J.L. Talc Committee
- CTFA

C O N F I D E N T I A L

DOMESTIC OPERATING COMPANY

NEW BRUNSWICK, N.J.

March 1, 1978

Mr. Charles Haynes
The Cosmetic, Toiletry and Fragrance Association, Inc.
1133 15th Street, N.W.
Washington, D.C. 20005

Dear Mr. Haynes:

I am enclosing a table which breaks the code for the recently completed CTFA Task Force on Round Robin Testing of Consumer Talcum Products for Asbestiform Amphibole Minerals. The names, addresses, and phone numbers are also included for those industrial participants whose products were involved.

In accordance with your discussions with Norm Estrin and George Sandland, Chairman CTFA Talc Subcommittee, we would request your assistance in the dissemination of these round robin results as follows:

1. Please contact me (201/524/5518) upon receipt of this letter so that I may destroy the only other copy of this table, which is in my possession.
2. Contact each of the industrial participants to inform them of the round robin results for their product only, as well as the actual lot tested. Please emphasize that no talcum product failed CTFA Method J4-1, Parts I and II; i.e., no product was found to contain asbestiform amphibole at a level equal to or greater than 0.5% by weight.
"Nonasbestiform Amphibole Detected" means that the product was found by CTFA Method J4-1 to contain only nonasbestiform amphibole at a level equal to approximately 0.5% or greater.

1978

J&J-0083118

JNJNL61_000062534

-2-

March 1, 1978

3. Destroy your copy of the table.

Your participation in this final important phase of
the round robin is appreciated. Thank you very much.

Sincerely,



John P. Schelz Chairman
CTFA Task Force on
Round Robin Testing of
Consumer Talcum Products

JS/gm
Enclosure

cc (without table): Dr. N. F. Estrin
Vice President-Science, CTFA
Mr. G. Sandland
Bristol-Myers Products

J&J-0083119

JNJNL61_000062535

Exhibit 169



June 27, 1995

SUBJECT: CTFA Response to Cancer Prevention Coalition Citizen's Petition

B. Fleming	J. O'Shaughnessy
C. Hammes	K. Schroeder
J. Freedman	M. McTernan
J. Hopkins	N. Matheson
J. Leebaw	N. Musco
J. Nugent	W. Slivka

This forwards a copy of the subject response (submitted to FDA June 9, 1995) for your information and use.

The response was developed by members of the Talc Interested Party Task Force, edited by Dr. Steve Gettings, and reviewed by CTFA legal. As you might guess, we played a significant role in writing, editing, and providing references for the comments. Mike Chudkowski and consultants Bill Ashton and Dr. Al Wehner all contributed a great deal to the final product.

As you will see when reading the response, the petition addressed issues which had been thoroughly examined in January 1994 in a two-day FDA sponsored workshop. The comments we made point out the conclusion of the workshop participants - that cosmetic talc is safe for consumer use.

I will keep you informed of any response we receive. For perspective, the last talc citizen's petition was in FDA review for three years before a response was published.

A handwritten signature in black ink that appears to read "Donald F. Jones, Jr."

Donald F. Jones

es
Enclosure

cc: W. Ashton
M. Chudkowski
A. Wehner

0037w.dj

**COMMENTS
OF
THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION
IN RESPONSE TO
A CITIZENS PETITION
FILED WITH
THE FOOD AND DRUG ADMINISTRATION
ON NOVEMBER 17, 1994
WHICH WOULD REQUIRE CARCINOGENIC LABELLING
ON ALL
COSMETIC TALC PRODUCTS**

FDA Docket No. 94P-0420/CP 1

June 1995

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IV. CONCLUSIONS

V. REFERENCES

I INTRODUCTION

The Cosmetic, Toiletry, and Fragrance Association (CTFA)¹ is filing these comments in response to a citizens petition filed by Ms. Jill A. Cashen and Samuel S. Epstein, M.D. on behalf of the Cancer Prevention Coalition ("Petitioner") on November 17, 1994 (FDA Docket No. 94P-0420/CP 1). Petitioner urges the Food and Drug Administration (FDA) to require "cosmetic talcum powder" products to bear labels with warnings such as "Talcum powder causes cancer in laboratory animals. Frequent talc application in the female genital area increases the risk of ovarian cancer". CTFA contends that such labelling is without scientific basis and is unnecessary to protect the health of consumers.

Talc (CAS No. 14807-96-6) comprises pulverized, natural, foliated, hydrous magnesium silicates (Harvey, 1988). As a pure mineral compound, talc is mineralogically defined as hydrous magnesium silicate, with the approximate chemical formula:



The largest commercial uses of talc are in industrial applications such as paint, plastics, paper, ceramics, and construction materials. Talc utilized in direct cosmetic applications accounts for a relatively small percentage of the overall talc market. In 1992, approximately 48,000 tons of talc were used in the United States for cosmetics, pharmaceuticals, and food products (American Westmin, Inc./Luzenac America, unpublished data).

Pharmaceutical tabletting and various food applications account for approximately 8% of

¹The Cosmetic, Toiletry, and Fragrance Association is the national trade association representing the cosmetic, toiletry and fragrance industry in the United States. CTFA, founded in 1894, represents over 500 companies involved in the personal care products industry. CTFA's active members manufacture and distribute the vast majority of personal care products marketed in the United States. CTFA's associate member companies supply goods and services such as raw materials and packaging to the industry's manufacturers and distributors. The personal care products industry prides itself on a long history of providing safe, reliable products to meet the diverse needs and personal tastes of the American consumer.

direct consumer uses of talc products; the greatest proportion (approximately 92%) is used in cosmetic applications. Used for decades in a wide variety of cosmetic and other applications, talc has proven to be among the safest of all consumer products. The talc industry has adopted stringent quality assurance standards set by the Food Chemical Codex, the United States Pharmacopeia and the Cosmetic, Toiletry and Fragrance Association. The focus of all three specifications is similar in that they place limits on certain extractable elements and other potential chemical contaminants. Only relatively pure talc products are capable of meeting these specifications.

Petitioner contends that labelling of cosmetic talc products is required in order to adequately warn consumers of the risk of ovarian cancer. However, the available literature and the experience of manufacturers provides no evidence that cosmetic talc, when used as intended, presents any health risk to the consumer. All current available safety information on cosmetic talc has been thoroughly reviewed (Wehner, 1994). Moreover, a panel of experts at a workshop organized by FDA and the International Society of Regulatory Toxicology and Pharmacology (IS RTP) convened to review the latest toxicological and epidemiological studies on talc concluded that the "probability of human risk [from talc] is likely non-existent under customary conditions of use" and that "while some weak association between talc exposure and ovarian tumors has been reported, it [is] not sufficient warning for concern" (Carr, 1995).

In summary, there is no evidence to suggest that cosmetic-grade talc is a human carcinogen and in particular there is no convincing evidence to show that frequent talc application in the female genital area may increase the risk of ovarian cancer. Specifically, CTFA will show that:

- the contention that cosmetic-grade talc contains asbestos is unsupportable;

- talc is a rat carcinogen only under conditions which produce particle overload and related chronic toxicity;
- consumer exposure to respirable talc particles is several orders of magnitude lower than exposures which result in rat lung tumors;
- evidence for the role of intrinsic and extrinsic risk factors in the etiology of ovarian epithelial cancer is inconclusive;
- epidemiological evidence supports only a weak statistical association between perineal talc use and ovarian cancer, the significance of which is not considered meaningful; and
- any weak statistical association is unsupported by evidence of a plausible biological mechanism by which talc could cause ovarian cancer.

In short, there is no scientific justification to support the Petitioners contention that cosmetic talc products should bear labels warning that "[t]alcum powder causes cancer in laboratory animals" and that "[f]requent talc application in the female genital area increases the risk of ovarian cancer".

II. THERE IS NO EVIDENCE TO SUGGEST THAT COSMETIC-GRADE TALC IS A HUMAN CARCINOGEN

A. The Contention that Cosmetic-Grade Talc Contains Asbestos is Unsupportable

Petitioner contends that talc used in cosmetic applications contains asbestos. This contention is based on outdated and erroneous evidence which FDA has previously refuted. Petitioner quotes early mineralogical research done by Cralley *et al* (1968) and Rohl *et al* (1976)

which sought to identify asbestos contamination in cosmetic talc. During the early 1970's FDA became concerned that cosmetic talc contained significant amounts of asbestos. However, in response to an earlier Citizens Petition "... FDA considered all analytical results to be of questionable reliability. This assessment proved to be correct because many questions were subsequently raised about results reported in the literature in the early 1970's" (letter from FDA Acting Associate Commissioner for Regulatory Affairs, 1986). In denying the Petition, FDA noted "we find that there is no basis at this time for the agency to conclude that there is a health hazard attributable to asbestos in cosmetic talc" (*Id.*).

The historical association between talc and asbestos is an extremely unfortunate one. Precipitated in large part by the use of overly broad definitions of asbestos and nonspecific analytical techniques (Rohl, 1974; Rohl and Langer, 1974; Krause and Ashton, 1978; Parmentier and Gill, 1978), the idea that asbestos is commonly and intimately associated with talc is simply incorrect. As a retrograde mineral, talc may be found in association with chrysotile in serpentinites and other hydrous minerals. However, the geologic conditions under which talc and asbestos form are dissimilar. Many talc-bearing rocks form from ultramafic rocks, the central core of which is composed of serpentinite surrounded, successively, by shells of talc-carbonate rock and talc-bearing steatite (steatite is synonymous with soapstone). Usually a thin wall schistose rock, composed essentially of chlorite, separates the steatite from the country rock. The serpentinite is composed mostly of non-fibrous serpentine minerals (lizardite and antigorite), but small amounts of chrysotile asbestos may also occur within the serpentinite. The talc-carbonate and steatite shells which surround the serpentinite core contain abundant talc but do not contain asbestos. Careful mining procedures enable the serpentinite core to be avoided and thus possible contamination of talc ore with asbestos is obviated. Confirmation of the absence of asbestiform

minerals in the finished talc product is established using x-ray diffraction, optical microscopy and electron microscopy techniques (CTFA, 1990).

B. Talc is a Rat Carcinogen Only Under Conditions Which Produce Particle Overload and Related Chronic Toxicity

Petitioner contends that "[t]alc is a carcinogen, with or without the presence of asbestos-like fibers". In support of this contention, Petitioner relies on the results of studies published by the National Toxicology Program (NTP). Petitioner's reliance is misplaced in that NTP showed talc to be a rat (but not a mouse) carcinogen, and only under circumstances indicative of a secondary mechanism involving particle overload and resultant chronic toxicity. In 1992, NTP reported the results of 2 year inhalation studies designed to determine the effect of talc in experimental animals (NTP, 1993); male and female F344/N rats and B6C3F₁ mice were exposed to target aerosol talc concentrations of 0, 6, or 18 mg/m³ for 6 hours/day, 5 days/week, for 2 years. NTP concluded that:

Under the conditions of these inhalation studies, there was some evidence of carcinogenic activity of talc in male F344/N rats based on an increased incidence of benign and malignant pheochromocytomas of the adrenal gland. There was clear evidence of carcinogenic activity of talc in female F344/N rats based on increased incidences of alveolar/bronchiolar adenomas and carcinomas of the lung and benign and malignant pheochromocytomas of the adrenal gland. There was no evidence of carcinogenic activity of talc in male or female B6C3F₁ mice exposed to 6 to 18 mg/m³.

Since its publication, the findings of NTP have been criticized by several experts in the field of inhalation toxicology with regard to both study design and conduct. Most notably these

studies were the subject of a joint ISRTIP/FDA scientific workshop held in 1994 (*Talc: Consumer Uses and Health Perspectives*; January 31/February 1, 1994) which discussed the relevance of the NTP findings with regard to consumer exposure and consumer safety. Criticisms of the study made at the workshop may be summarized as follows:

Test Article/Particle Size: The NTP study has questionable relevance with regard to prediction of human risk due to consumer exposure since the talc sample utilized in the NTP study was of a kind which is used in industrial applications, and was not a product that would be used in a cosmetic powder application because of its extreme fineness (Zazenski et al., 1995). The test material used by NTP is an industrial grade product typically used in specialty coatings and high performance polymeric applications. The median particle size of the NTP talc sample was approximately 1.2 microns and had a top size of approximately 10 microns. In contrast, typical commercial loose talc powder has a median particle size of approximately 10 microns and a top size of approximately 45 microns (Zazenski et al., 1995).

Exposure Levels Resulted in Lung Particle Overload: The major criticism of the NTP study is the failure to include exposure levels which did not lead to lung particle overload. The concept of "particle overload" in chronic inhalation studies with highly insoluble particles of relatively low toxicity is now widely accepted (Morrow, 1988). Typically, exposure concentrations are relatively high and result in retained particulate lung burdens which are also high. Such retained lung burdens lead to a sequence of inflammatory responses, altered particle-clearance/retention and altered morphology, leading to chronic disease states including fibrosis and the induction of benign/malignant tumors (see Oberdörster, 1995).

Highly insoluble particles deposited in the lower respiratory tract are removed by two important mechanisms (see Oberdörster, 1995). The mucociliary escalator removes particles

deposited in the conducting airways; particles deposited in the alveolar region are phagocytosed by alveolar macrophages (AM) which then migrate towards the mucociliary escalator and are removed (Schlesinger, 1985, Oberdörster, 1988; Snipes, 1989). When deposition rate in the alveolar region exceeds the AM-mediated clearance rate, alveolar retention halftime is considerably increased (often irreversibly) and results in excessive accumulation of particles in the lung. One further consequence of excessive accumulation is increased translocation of particles to the pulmonary interstitium which eventually results in the induction of pulmonary fibrosis (Adamson et al., 1989; Bowden et al., 1989), activation of macrophages and release of cytokines resulting in increased epithelial cell proliferation (Driscoll et al., 1990).

Based on the actual talc burdens of exposed rats (ie., as measured by NTP), Oberdörster (1995) has estimated that the pulmonary retention halftimes of the retained talc particles range between 250 and 300 days, ie., is markedly longer than the normal retention halftime for highly insoluble particles in rat lungs of ~70 days. Oberdörster has concluded that these results are indicative of lung particle overload. Oberdörster has also shown that the talc-exposed mice exhibited a marked increase in pulmonary retention halftime for talc particles with increasing lung burdens (i.e., a severe retardation of normal AM-mediated particle clearance) compared to a normal retention halftime in mice lungs. In summary, the lung particle clearance was impaired in both rats and mice in the NTP study, resulting in altered accumulation kinetics of talc particles chronically inhaled at concentrations of 6 and 18 mg/m³. The rat tumor response is thus very likely a secondary effect of the particle overload phenomenon ie., due to altered lung clearance kinetics resulting in excessively high lung burdens leading to chronic inflammatory and cell proliferative processes (Oberdörster, 1995). Conceivably, the difference in tumor response between male and female rats may be merely temporal since hyperplasia and an interstitial fibrosis

was observed in both sexes. Oberdörster attributes the lack of pulmonary tumors in mice to the fact that rat lung tumors associated with a high pulmonary particle load appears to be a very species-specific response to non-fibrous particles (Oberdörster, 1995).

Exposure Levels Exceeded the MTD: The highest dose in carcinogenicity studies is generally designed to be equivalent to the maximum tolerated dose (MTD). Although this principle has become increasingly subject to criticism, high-dose testing at the MTD remains the practice of NTP. In general, the MTD is estimated following a careful analysis of data from appropriate subchronic toxicity tests. The need to consider a broad range of biological information when selecting the MTD has become increasingly clear. For example, data concerning changes in body/ organ weight, clinically significant alterations in hematologic, urinary and clinical chemistry measurements, as well as more definitive toxic, gross or histopathologic endpoints can be used to estimate the MTD.

For chronic inhalation studies with highly insoluble particles of low cytotoxicity, the phenomenon of particle overload and the question of exceeding the MTD are intimately interrelated. Recommendations of a NTP Workshop on Maximal Aerosol Exposure Concentrations in Inhalation Studies (Lewis *et al.*, 1989) included "[the] chronic study should *not* (emphasis supplied) be performed at the highest technologically feasible concentration, three concentrations should be used of which only the highest should show some interference with lung defense mechanisms, i.e., clearance impairment; and the two lower concentrations should show no interference with clearance and particle accumulation". Based on these criteria, the MTD was clearly exceeded in the studies conducted by NTP on talc.

In the NTP study, talc-induced lung tumors were not detected in male rats, female mice or male mice. In rats, the principal toxic lesions associated with inhalation exposure to talc included

chronic granulomatous inflammation, alveolar epithelial hyperplasia, squamous metaplasia and squamous cysts, and interstitial fibrosis of the lung. These lesions were accompanied by impaired pulmonary function. While the talc burden in the lungs of males and females was similar, the degree of chronic toxicity and inflammation was substantially higher in females. In mice, inhalation exposure to talc produced some chronic inflammation. In contrast to rats, alveolar epithelial hyperplasia, squamous metaplasia, and interstitial fibrosis were not observed. Overall, markedly less talc-induced lung toxicity was produced in mice than in rats. In summary, it is apparent that an increase in lung tumors was seen only in the test animals that clearly exhibited the highest degree of chronic lung toxicity, (ie., the female rats exposed to 18 mg/m³ talc). Similarly, the increased incidence of pheochromocytomas is most likely attributable to the stressful conditions (eg., as a result of physiological, metabolic or endocrine changes) to which the test animals were exposed. In addition, the F344/N rat is known to have a high background incidence of pheochromocytomas (NTP, 1993). The relevance of these responses with regard to extrapolation to humans is thus highly suspect (Goodman, 1995).

The unmistakable conclusion from these observations is that the MTD was exceeded in the female rats exposed to the high dose, and that talc is not expected to cause lung tumors under conditions of exposure that fail to result in marked chronic lung toxicity (Goodman, 1995). In contrast to Petitioner's characterization of the results of the NTP study, clear evidence of carcinogenic activity of talc was seen *only* in female rats (not male or female mice) exposed to the high dose of talc and *only* under circumstances in which there was evidence of particle overload and marked chronic lung toxicity. In summarizing its assessment of the NTP study, the panel of experts at the IS RTP/FDA workshop *Talc: Consumer Uses and Health Perspectives* characterized the positive results in female F344/N rats as "likely experimental artifact...[a] non-

specific generic response of dust overload of the lungs, and not a reflection of a direct activity of talc. Given the gross differences of rodent and human lungs, the lung clearance capabilities of humans and the possible conditions of customary human exposures, the NTP bioassay results in F344/N rats cannot be considered as relevant predictors of human risk" (Carr, 1995).

C. Consumer Exposure to Respirable Talc Particles is Several Orders of Magnitude Lower Than Exposures Which Result in Rat Lung Tumors

Although Petitioner would require warning labels to the effect that "[t]alcum powder causes cancer in laboratory animals", the implication is that talc exposure constitutes human risk of cancer. Such an implication is unwarranted since consumer exposure to talc is considerably lower than exposures which result in rat lung tumors. Consumers are exposed to talc during the application and use of body powders. In this regard, human exposure occurs principally via the dermal route, but primary concern has focused on exposure via the respiratory tract. Talc miners and millers are exposed to long-term, relatively high concentrations of airborne talc; the results of human cohort studies involving cosmetic grade talc miners and millers thus provide a useful basis against which pulmonary risk to consumers may be estimated (Scansetti et al., 1963; El-Ghawabi et al., 1970; Rubino et al., 1976; Gamble et al., 1982; Wegman et al., 1982; Leophonte et al., 1983; Wergeland et al., 1990). These studies show that a pneumoconiosis (talcosis) risk does exist but only when respirable talc dust levels are significantly greater than worst-case consumer exposures (described below) and exposure is over an extended period of time (several years).

While there may be disagreement over the amount of exposure required to induce pneumoconiosis, such studies suggest that talc poses a low to moderate pulmonary risk in an industrial setting. For example, in a mortality and morbidity study of Italian talc miners and millers, radiographic abnormalities consistent with pneumoconiosis were found among talc

workers after an average duration of exposure for 22 years, with an average respirable dust concentration of approximately 11 mppcf (Rubino, et al., 1976); in contrast, in a study involving French talc workers, no cases of pneumoconiosis at a level of 15 mppcf were reported (Leophonte, et al., 1983). Although it is difficult to reliably convert respirable particle count data (mppcf) into respirable gravimetric data (mg/m³), such levels typically fall into the 1-2 mg/m³ range (e.g., in a study of Vermont talc miners and millers (Boundy et al., 1979), pneumoconiosis was observed when respirable dust levels ranged from 0.5 to 2.9 mg/m³). Despite the incidence of pneumoconiosis at high industrial exposure levels it is important to note that an excess prevalence of lung cancer in talc mining populations has not been observed (Selevan et al 1979; Leophonte et al., 1983; Wergeland et al., 1990; Rubino et al., 1976).

Electrostatic, Van der Waal's and valance charges present on the particulate surfaces of a dry powder such as talc result in substantial particle-to-particle agglomeration, thereby increasing effective mass, diameter, and settling velocity (Carta et al., 1981; Gajewski, 1990). These factors are important with regard to influencing the respirability of dry particles. Two studies have been conducted to evaluate exposures to respirable particles during application of talc as an adult body powder and as a baby powder (Russell et al., 1979; Aylott, et al., 1979). In both studies, respirable particles (\leq 10 microns) were collected usig a cyclone particle fractionation system operating at an air flow rate of 1.7-1.9 liters/minute. Adult exposure was assessed during normal face/body powdering practices by placing cyclone collection units on shelves at appropriate face height, or by positioning a cyclone attached to a headband near the nose (i.e., in the subjects breathing zone). To evaluate the exposure of babies to talc, sampling units were placed on the changing table near the infants' (or doll's) heads during normal powdering practices (i.e., while changing a diaper). Talc was dispensed using common twist-top, sprinkle-type containers, or in

the case of face powder, powder puffs. Exposure of adults to respirable particles during application of talc ranged from 0.48 to 2.03 mg/m³, while the exposure to babies ranged from 0.19 to 0.21 mg/m³. When these numbers are extrapolated to 8-hour time weighted average exposures, they range from <0.001 to 0.005 mg/m³ (Zazenski et al., 1995). For comparison purposes, the current OSHA/ACGIH permissible industrial exposure limit for talc is 2.0 mg/m³ as an 8 hour time-weighted average (ACGIH, 1992), i.e., the industrial permissible limit is approximately 350 times greater than the worst case consumer use of cosmetic grade talc.

Based upon the determinations reported in the literature, human exposure to respirable talc particles during normal product use are approximately 2,000-20,000 times lower than those used to expose rats and mice in inhalation studies conducted by the NTP (Zazenski et al., 1995). Although a direct comparison of the dosimetry of inhaled materials between rodents and humans is far from simple (Dahl et al., 1991), such a broad difference in exposure level is quite striking. The incidence of tumors resulting from massive exposures such as those involved in the NTP talc inhalation study are more likely to reflect a particle overloading effect in the experimental animals (Morrow, 1988; Morrow, 1992; Oberdörster, 1988) than any genotoxic effect associated with the test material (Endo-Capron et al., 1993).

As previously noted, the talc sample utilized in the NTP study was not a product that would be used in a cosmetic powder application because of its extreme fineness (SECTION II. B). Further, the NTP talc aerosol was exposed to Kr-85 gamma radiation immediately prior to its introduction into the exposure chambers containing the experimental animals. Use of ionizing radiation was intended to neutralize the electrical charge imparted on the talc particles during aerosolization. Charge neutralization tends to decrease agglomeration and results in deposition of particles in the deep lung of exposed animals. Thus, while selection of an ultra-fine product

combined with procedures designed to maximize particle dispersion may be entirely appropriate from a toxicological perspective, such an artificial environment has questionable relevance with regard to actual human exposure from commercial cosmetic talc products under use conditions.

SECTION II. SUMMARY

The issues raised by Petitioner with regard to asbestos contamination of cosmetic-grade talc have previously been addressed by FDA. In 1986, FDA concluded that there was no health hazard attributable to asbestos in cosmetic talc. Since that time no new evidence has arisen which would suggest a conclusion to the contrary; moreover, appropriate selection of mine site, careful mining procedures and the utilization of modern beneficiation techniques have further safeguarded against asbestos contamination. Accordingly, CTFA believes that FDA's response to the issue of asbestos contamination raised by Petitioner should be no different than its response in 1986.

With regard to Petitioner's assertion that talc is an animal carcinogen, the NTP chronic inhalation study has been subject to severe criticism. The test material used by NTP was characterized by an extremely small particle size and is not characteristic of material used for cosmetic talc applications. Further, the exposure levels chosen by NTP clearly exceeded the MTD for talc and were such that exposure resulted in impairment of lung clearance mechanisms and a condition known as particle overload. Because any highly persistent particulate compound of low cytotoxicity has carcinogenic potential, particularly in rats, when chronically inhaled at such high concentrations, the classification of such particles with respect to pulmonary carcinogenicity must be carefully evaluated. In the absence of any evidence of a toxic or genotoxic effect *per se*, the only reasonable conclusion which may be drawn from the studies conducted by NTP is that the carcinogenic effect of talc is a secondary phenomenon which does

not occur in the absence of chronic toxicity which is itself a result of particle overload.

In summary, the application of the results of the NTP study with regard to human risk assessment are highly questionable. Consumer exposure to respirable talc particles is several orders of magnitude lower than exposures which result in rodent tumors. There is no evidence of chronic toxicity following consumer exposure to talc, thus use of the lung tumor endpoint in female rats as the basis of extrapolation to human risk is inappropriate. Clearly, Petitioner's request that FDA require warnings such as "[t]alcum powder causes cancer in laboratory animals", with it's implicit message that talc may cause human risk of cancer, is both misleading and may cause consumers unnecessary concern. As such, Petitioner's request should be denied.

III. THERE IS NO CONVINCING EVIDENCE TO SUPPORT THE CONTENTION THAT FREQUENT TALC APPLICATION IN THE FEMALE GENITAL AREA MAY INCREASE THE RISK OF OVARIAN CANCER

A. Evidence For The Role Of Either Intrinsic Or Extrinsic Risk Factors In The Etiology Of Ovarian Epithelial Cancer Is Inconclusive

The etiology of human ovarian epithelial cancer is not clearly understood. Ovarian tumors of epithelial origin, which include serous, mucinous, endometrioid, clear cell and undifferentiated adenocarcinomas and the Brenner tumor, are responsible for the majority of ovarian malignancies (Cannistra, 1993; Slotman and Roa, 1988). The purported extrinsic and intrinsic risk factors which contribute to the incidence of epithelial cancer of the ovary have been the subject of numerous reviews (Shoham, 1994; Kelsey et al., 1994; Dietl and Marzusch, 1993; Parazzini et al., 1991; Baylis et al., 1986; Heintz et al., 1985). While a number of scientists have attempted to identify various extrinsic risk factors, including environmental (e.g. tobacco and talc), infectious disease (e.g. mumps, rubella), and dietary intake (e.g. lactose, animal fat, alcohol, caffeine) as

potential etiologic agents, the data are inconclusive. At best, some studies have demonstrated a relationship between dietary factors and the incidence of ovarian epithelial cancer; in particular, an increased risk for ovarian cancer has been reported for women who consume diets which are high in animal fat (Shu et al., 1989; Mori and Miyake, 1988; La Vecchia, et al., 1987) and lactose (Cramer, 1989; Cramer et al., 1989).

Research investigating intrinsic risk factors has provided evidence which suggests that reproductive history and molecular factors are strongly linked to carcinogenesis of the ovarian epithelium. It is well documented that suppression of ovulation, either by pregnancy or by oral contraceptive use, decreases the risk for developing ovarian cancer (McGowan et al., 1979; Wu et al., 1988; Mori et al., 1988; Booth et al., 1989). Ovulation is a physiologic process which is mediated by hormones (gonadotropins) and results in repeated ruptures in the surface epithelia of the ovary. Following ovulation, a repair process takes place whereby there is an increase in epithelial cell mitotic activity. The reduced risk afforded by pregnancy or by oral contraceptive use is postulated to be mediated by the subsequent decrease in circulating gonadotropins and/or the suppression of ovulation (Whittemore, et al., 1992). Evidence supporting the etiologic role of ovulation has been provided by *in vitro* studies demonstrating that the repeated cell division of ovarian surface epithelial cells results in a malignant transformation (Godwin et al., 1993).

Molecular events associated with the initiation of ovarian cancer have recently been reviewed (Berek and Martinez-Maza, 1994; Godwin et al., 1993). Genetic mutations are molecular events which can lead to tumor formation. Studies assessing family history have reported a genetic predisposition to ovarian cancer (Patel and Obrams, 1993; Hartge et al., 1989) which appears to be inherited on an autosomal dominant gene (Slotman and Rao, 1988). Specific loss of a gene at the 6q chromosomal loci has been identified in ovarian tumors (Lee et al., 1990);

additionally, genetic alterations on chromosomes 1,3, 14 and 17 have been identified in certain ovarian carcinomas (Daly, 1992). Mutations can result in chromosome alterations and the subsequent inactivation of a particular gene. Studies conducted by Hoffman and colleagues (1993) have demonstrated a reduced expression of a cell adhesion molecule (E-cadherin) in an *in vitro* model of ovarian epithelial carcinogenesis. Genetic alterations can also lead to the overexpression of a gene. Proteins encoding certain chemical messengers (cytokines), such as IL-6 (interleukin 6), M-CSG (macrophage colony stimulating factor) and TNF (tumor necrosis factor) have been found to be increased in epithelial ovarian cancer cells (Malik and Balkwill, 1991).

In summary, the events which lead to development of ovarian epithelial cancer are not clearly understood. A variety of intrinsic and extrinsic risk factors may be involved. However, in light of the fact that cancer is a disease which evolves at the molecular level, it is likely that research investigating the molecular aspects of ovarian cancer may provide important insight how such risk factors relate to incidence. It is significant in this respect that a thorough review of the toxicology of talc reveals no evidence any genotoxicity (Wehner, 1994).

B. Epidemiological Evidence Suggests Only a Weak Statistical Association Between Perineal Talc Use and Ovarian Cancer, the Significance of Which is Not Considered Meaningful

Although several studies on the possible association between perineal talc use and ovarian cancer have been published, any evidence of such an association remains equivocal. At most, the statistical association is weak and in the absence of evidence of a plausible biological mechanism (SECTION III. C) is insufficient to warrant public health concern. There have been seven case-control studies and one cohort study that have been published containing information regarding

the risk of ovarian cancer in women using talc in their perineal region (Cramer et al., 1982; Hartge et al., 1983; Whittemore et al., 1988; Booth et al., 1989; Harlow and Weiss, 1989; Harlow et al., 1992; Rosenblatt et al., 1992; Hankinson et al., 1993). Talc exposure was the primary focus in only four of these studies (Cramer et al., 1982; Hartge et al., 1983; Harlow and Weiss, 1989; Harlow et al., 1992).

Cramer *et al* (1982) investigated whether there is an association between exposure to certain hydrous magnesium silicates (including talc), and the incidence of ovarian cancer. Population-based matched controls were randomly selected, and stratification and logistic regression were used to accommodate confounders. Overall, 42.8% of cases and 28.4% of controls reported exposure to talc, via direct application to the perineum, by dusting sanitary napkins, or both. The unadjusted odds ratio (OR) of ovarian cancer for any perineal exposure as opposed to no perineal exposure was 1.89 (95% CI 1.27-2.82). Adjustment was then made for parity and menopausal status. Women who used talc on both the perineum and sanitary napkin had an adjusted OR of 3.28 (95% CI 1.68-6.42) and for any exposure, 1.61 (95% CI 1.04-2.49). The reduction in risk from 1.89 to 1.61 for perineal talc exposure due to logistic regression is largely unexplained and may be due to residual confounding. No dose-response or duration data were reported. While a major strength of the study is the use of neighborhood controls, the nonparticipation rate among controls was relatively high (260/475=55%).

Hartge *et al* (1983) investigated the association between talc use and the risk of ovarian cancer but reported no significant finding. The cases were women with pathologically confirmed primary epithelial ovarian cancer, while the hospital based controls had non-gynecological conditions (psychiatrically disturbed women, pregnant women, and women with other malignancies were excluded). Controls were frequency matched on age, race and hospital. For

the group of women who did not use talc versus the group of women who did, the unadjusted OR of ovarian cancer was 0.776 (95% CI 0.47-1.20). Although no attempt was made to control for potential confounding variables, this nonsignificant odds ratio was unaffected by adjustment for parity, race and age.

Lifetime consumption of coffee, tobacco and alcohol were the principal exposure factors studied by Whittemore *et al* (1988). Women diagnosed with ovarian cancer in the San Francisco Bay area between 1983-5 provided the cases for this study. Matched controls from two groups, hospital and population, were obtained. The hospital controls were selected from the same hospitals as the cases, whereas the population controls were selected using random digit dialing. All controls were matched to cases on age, race, and having at least one ovary. Logistic regression was used to adjust for confounders. While this study examined other potential risk factors as well as talc exposure in relation to ovarian cancer, the study did not find evidence of an association between genital talc exposure and an increased risk of ovarian cancer. While women who reported regular use of talc on the perineum showed a marginally significant increase in relative risk, no other differences were noted between cases and controls when considering other types of perineal talc exposure either alone or taken in combination. The unadjusted OR of ovarian cancer for any perineal exposure as opposed to no perineal exposure was 1.19 (95% CI 0.85-1.66). Adjusted for parity, the OR was 1.40 (95% CI 0.98-1.99). Other odds ratios also failed to produce significant associations. Several sources of bias were identified, including failure to interview all eligible cases, the potential pitfalls in combining hospital and population controls, confounding by differential talc use among women with characteristics predictive of ovarian cancer and random error in reported talc use tending to attenuate relative risk estimates. The study raises the possibility that a hormonal factor that may place women at a higher risk for the

disease may also promote their use of talc.

Booth *et al* (1989) studied various potential risk factors for ovarian cancer including infertility, oral contraceptive use, parity, age at menopause, and genital talc use. Women with a diagnosis of ovarian cancer and treated at a London cancer hospital were each age matched to two hospital controls at 15 other hospitals. Non-participation rates were not provided, and one hospital providing more than 25% of the cases provided no controls. In addition, cases were generally older and in a higher social class than controls. All odds ratios were adjusted for social class in six categories. Maximum likelihood estimates of the odds ratios with the corresponding 95% confidence intervals were obtained. Logistic regression was used to test for trends. The results were inconclusive since weekly talc use showed a higher OR of ovarian cancer (2.0) than did daily use (1.3), (95% CI 1.3-3.4 and 0.8-1.9, respectively). Furthermore, there was no significant difference between cases and controls who used talc in conjunction with a diaphragm. The unadjusted OR of ovarian cancer with regard to talc use was a statistically nonsignificant 1.29 (95% CI 0.92-1.81). Overall, the study does not support the hypothesis that use of perineal talc increases the risk of ovarian cancer.

Harlow and Weiss (1989) investigated whether application of perineal talc application is associated with an increased risk of serous and mucinous borderline ovarian tumors. Cases (residents of three urban, western Washington state counties diagnosed as having a serious or mucinous borderline ovarian tumor) were identified from the corresponding population-based cancer reporting system. Controls were population-based and located through random digit dialing. Women who reported any perineal use of dusting powders had an adjusted OR of 1.1 (95% CI 0.7-2.1) for borderline ovarian tumor. The adjustment was for age, parity, and use of oral contraceptives but not for other possible confounders. Women using deodorizing powder

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with or without baby powder (the only powder reported by women using a second powder) showed an increased risk of borderline tumor development, OR of 2.8 (95% CI 1.1-11.7). The elevated risk of borderline ovarian cancer among women who specifically used deodorizing powders may have been due to chance or applicable only to borderline but not malignant tumors.

Harlow *et al* (1992) investigated whether the use of talc increases the risk for epithelial ovarian cancer. Between July, 1984, and September, 1989, cases were diagnosed with borderline or malignant epithelial ovarian cancer at 10 different Boston metropolitan hospitals. Population controls were age matched and were all Caucasian. The influence of confounders and effect modifiers was assessed through stratification and logistic regression. Overall, 49% of cases and 39% of controls reported exposure to talc, yielding an OR of 1.5 (95% CI 1.0-2.1) for ovarian cancer. Among women with perineal exposure to talc, the risk was significantly elevated in subgroups of women who applied it directly as body powder (OR of 1.7; 95% CI 1.1-2.7). Women with an intact genital tract (and who had at least 10,000 applications while ovulating) showed an OR of 2.8 (95% CI 1.4-5.4). Although this study seemingly suggests a small increased risk of epithelial ovarian cancer due to lifetime use of perineal talc, the association is still not entirely clear. One important potential confounder that was not accounted for in this study was oral contraceptive use. More controls used oral contraceptives than cases, and oral contraceptive use was associated with less reported talc exposure. Thus, use of oral contraceptives is a possible strong confounder that, if properly considered, could eliminate any observed effect.

Rosenblatt *et al* (1992) studied the relationship between "fiber" exposure (Note: these investigators mischaracterize talc as "fiber"; other exposures include asbestos and fiberglass) and epithelial ovarian cancer. Controls, who were hospital-based and free of gynecological and malignant conditions, were matched to cases by age, race and date of diagnostic admission. Due

to the strict inclusion criteria, controls could not be found for each case. Thus although 140 new cases were located and 108 were successfully interviewed, only 77 cases were entered into the study. The OR (adjusted for number of live births) was 1.0 (95% CI 0.2-4.0) for women reporting any genital "fiber" use versus those women who were not so exposed; the unadjusted OR was 0.84 (95% CI 0.27-2.63). An increased risk of ovarian cancer was observed for women who used talc on their sanitary napkins with an OR of 4.79 (95% CI 1.29-17.79). However, among the remaining eight odds ratios, none was statistically significant. While there seems to be an elevated risk of ovarian cancer in women who used talc on sanitary napkins, this finding is not supported by other studies (eg., Harlow *et al.*, (1992) did not report an elevated risk in this category).

The most recent study in which an indirect comparison of ovarian cancer incidence in talc users versus nonusers can be made was reported by Hankinson *et al* (1993). The purpose of this study was to assess whether tubal ligation and hysterectomy affected subsequent risk of ovarian cancer based upon the hypothesis that such procedures could prevent translocation of talc to the ovaries. In reporting a finding of no association between talc use and an increased risk of ovarian cancer the authors found that tubal ligation was "highly protective in women who reported never using talc". Such a finding tends to discount the talc translocation hypothesis discussed in SECTION III.C, below).

In reviewing evidence of the proposed association of talc exposure and ovarian cancer, the panel of experts at the ISRTP/FDA workshop *Talc: Consumer Uses and Health Perspectives* found that the "epidemiologic data are conflicting and remain equivocal" (Carr, 1995). The panel noted the problems connected with the epidemiology of weak associations and the fact that any properly designed study to determine the association between perineal talc use and ovarian cancer

must account for other possible risk factors. These other factors include (but are not necessarily limited to) age, oral contraceptive use, number of term pregnancies, menopausal status, and other, environmental factors such as smoking status, alcohol and caffeine consumption. Other confounding variables, such as vulvovaginal diseases and obesity may also be causally related to ovarian cancer (Rosenblatt et al., 1992). In such instances (where talc use is associated with such conditions because of the degree of comfort it imparts to those affected), any statistical association between talc use and ovarian cancer may be merely coincidental.

In summary, the results of epidemiological studies are inconsistent and ambiguous. Any reported association between perineal talc use and ovarian cancer is weak and statistically barely significant. The biological significance (and hence public health significance) of any such weak association remains obscure.

C. Any Weak Statistical Association is Unsupported by Evidence of a Plausible Biological Mechanism by Which Talc Could Cause Ovarian Cancer

As previously described (SECTION III. B), several investigators have proposed that, based on weak epidemiological evidence, chronic perineal use of talc, including direct application or application to under garments, sanitary napkins or diaphragms, may increase the risk of ovarian cancer. In order for this to occur, talc particles (which have no inherent locomotive capability) would have to migrate from the perineum to the ovaries of exposed individuals. In order to try to identify such a potential translocation process, several studies have been conducted in various species, including humans. Many of these studies are so fraught with problems as to render the results of such studies ambiguous.

Egli and Newton (1961) have claimed that half an hour following vaginal deposition of carbon black particles, translocation occurred from the vagina to the oviducts in two of three

female patients. The results of this study are subject to considerable doubt since the investigators failed to utilize either solution or filter blanks as negative controls. Wehner *et al* (1985) subsequently conducted a similar study in cynomolgus monkeys and found no difference in the number of carbon black particles in the blanks compared to the oviduct rinse solution.

In a study conducted by De Boer (1972), carbon black particles were deposited in the uterus, cervical canal, or vagina of over 100 patients prior to abdominal surgery. Subsequent evaluation showed that when deposited in the uterus, carbon black particles translocated to the oviducts and beyond; particles placed in the cervical canal migrated to a lesser extent. Translocation from the vagina occurred in only 2 of 37 patients: in both cases the patients were placed in the Trendelenburg position, resulting in a negative intra-abdominal pressure. Such negative pressure was considered by the investigator to have been sufficient to draw up material from the vagina, especially when the patient was anesthetized and had a relaxed cervix.

Translocation studies have also been performed in laboratory animals. Henderson *et al* (1986) injected a suspension of talc particles into the cervical canal of 8 female ex-breeder Sprague-Dawley rats. A group of four animals was sacrificed 5 days later, while the remaining 4 animals received additional installations 6 and 15 days following initial treatment. Two of these animals were further administered the talc suspension at 22 and 30 days; six other animals received intra-vaginal injections of talc particles. Subsequent evaluation showed that all animals receiving intrauterine deposition of talc (and 2 of 6 receiving intra-vaginal administration) resulted in the detection of talc particles in the ovaries. Wehner (1994) has suggested that the hydrostatic pressure of the saline solution enhanced the potential for translocation under such conditions. In contrast Phillips *et al* (1978) found no radiolabel in the ovaries of rabbits given either single or multiple intra-vaginal doses of ³H-labelled talc.

An attempt to quantify the amount of talc supposedly found in human ovarian tissue (normal ovaries, cystic ovaries, and ovarian adenocarcinomas) has been made by Henderson *et al* (1979). According to these investigators, normal ovarian tissue contained up to 55,100 particles of talc per gram of wet weight of tissue, while cystic ovaries and ovarian adenocarcinomas contained up to 24,300 particles. However, because talc is ubiquitous, especially in a laboratory or surgical setting, it is difficult to determine if the talc observed in such clinical specimens is due to a specific exposure or contamination. In order to specifically and clearly evaluate the potential for translocation of talc from the vagina to the ovaries, Wehner *et al.* (1986) used neutron-activated talc with subsequent gamma-ray analysis in order to rule out contamination. These investigators used cynomolgus monkeys since the physiological and anatomical characteristics of this species resembles the human female more closely than any other readily available laboratory animal (cynomolgus monkeys have an estrous cycle of 28 days and menstruation lasts 2-7 days). Neutron-activated talc was deposited in the vagina for 30 consecutive working days (45 calendar days); thus exposure occurred through at least one menstrual cycle. Oxytocin was administered once per week during the study to induce the type of uterine contractions thought to occur during coitus and which may enhance the translocation process. The vagina/cervix, uterus, oviduct, ovaries and peritoneal lavage fluid of exposed animals were subsequently examined. Talc was observed only at the site of administration (vagina/cervix) and none was found in the ovaries.

In the carcinogenicity studies conducted by NTP (see SECTION II. B) male and female F344/N rats and B6C3F1 mice were exposed to target aerosol concentrations of 0.6 and 18 mg/m³ talc for 6 hours daily, 5 days per week, for two years. Such conditions resulted in exposure via inhalation, oral and dermal (including perineal) routes. Initial tissue examination found no exposure-related lesions in either rat or mouse ovaries (NTP, 1993). Subsequent

histological examination of the ovaries and ovarian bursa from rats confirmed this finding and demonstrated no material consistent with the appearance of talc in any animals from any group (Boorman and Seely, 1995).

In summary, available histologic and physiologic studies provide no concrete basis to conclude that talc can plausibly migrate to the ovaries from the perineal region. In the absence of such biological evidence, conflicting and equivocal evidence of a weak statistical association between perineal talc use and ovarian cancer is insufficient to "raise concern at level sufficient to warrant regulatory or public health measures" (Carr, 1995).

SECTION III SUMMARY

Although several possible intrinsic and extrinsic risk factors have been suggested, the etiology of ovarian epithelial cancer is presently unknown. Critics of the supposed association between talc and ovarian cancer highlight the reported weak associations and the numerous confounding variables (e.g., interview case/control comparisons, failure to adequately address key independent risk factors, etc.) which characterize much of the epidemiological research in this area. Further, experimental studies in which neutron-activated talc was repeatedly introduced into the vagina of cynomolgus monkeys, failed to demonstrate translocation to the cervix, uterus or ovaries. The results of these studies in monkeys suggest that any increased risk of ovarian cancer following perineal exposure to talc is biologically implausible. While deserving of further study, a causal association between perineal talc application and ovarian cancer appears improbable at this time.

IV. CONCLUSIONS

In January 31- February 1, 1994, a workshop organized by FDA and the International Society of Regulatory Toxicology and Pharmacology (IS RTP) was convened to provide a forum for an updated discussion of the origins, manufacture, characterization, toxicology and epidemiology of talc.² The principal focus of the meeting was on the latest toxicologic and epidemiologic studies and their significance with regard to the safe uses of talc in consumer products.

At the conclusion of the workshop, a panel of independent experts were able to reach a series of unanimous conclusions. With regard to the NTP talc bioassay in rodents, the panel found that "because of the extreme doses and the unrealistic particle sizes of the talc employed, because of the negative results in mice and male rats, because of the lack of tumor excess at the low doses, and because of the clear biochemical and cytological markers of excessive toxicity in female rats, the positive talc bioassay results in female F344/N rats are likely the result of experimental artifact and a non-specific, generic response of dust overload of the lungs, and not a reflection of a direct activity of talc. Given the gross differences of rodent and human lungs, the lung clearance capabilities of humans and the possible conditions of customary human exposures, the NTP bioassay results in F344/N female rats cannot be considered as relevant predictors of human risk" (Carr, 1995).

With regard to the proposed association of talc exposure and ovarian cancer, the panel found that "epidemiologic data are conflicting and remain equivocal". "Diet, parity, contraceptive use, ovulatory frequency, familial predisposition, age to menarche and menopause amongst other factors [are] associat[ed] strongly (and plausibly) with ovarian cancer incidence" (Carr, 1995).

²These conclusions are in large part based upon an Executive Summary which prefaced a series of papers published as the proceedings of the FDA/IS RTP Conference, *Talc: Consumer Uses and Health Perspectives* (Carr, 1995).

These possible confounders, as well as control selection biases, etc., interviewer and interviewee biases, as well as other factors, may well explain the conflicting results that have appeared in the literature. In summary "...epidemiologic studies have provided weak and conflicting risk signals for [the] association [between talc use and ovarian cancer], and it is unlikely that further studies may prove adequate to raise concern at a level sufficient to warrant regulatory or public health measures " (Carr, 1995).

In conclusion, there is no basis to Petitioner's request that cosmetic talc products should bear warning labels to the effect that talcum powder causes cancer in laboratory animals or the "[F]requent talc application in the female genital area increases the risk of ovarian cancer". When used as intended, talc presents no health risk to the consumer. Accordingly Petitioner's request for warning labels on talc-containing cosmetic products should be denied.

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